

NEI 14-05A, Revision 1-A

**GUIDELINES FOR THE USE
OF ACCREDITATION IN
LIEU OF COMMERCIAL
GRADE SURVEYS FOR
PROCUREMENT OF
LABORATORY
CALIBRATION AND TEST
SERVICES**

September 2020

ACKNOWLEDGEMENTS

This guidance was developed by the Nuclear Energy Institute (NEI) International Laboratory Accreditation Cooperation (ILAC) Task Force with the valuable assistance of the NEI Quality Assurance Task Force and the Nuclear Procurement Issues Committee (NUPIC) ILAC Committee under the leadership of Earl Mayhorn, AMEREN. The Electric Power Research Institute (EPRI) Joint Utility Task Group (JUTG) on commercial grade dedication (CGD) helped assure fidelity with CGD guidance was maintained, where appropriate. Members of ILAC also assisted in the review this document to assure the ILAC process is accurately described. We also recognize the direct participation of the licensees and suppliers who contributed to the development of the guidance. The dedicated and timely effort of the many participants, including management support of the effort, is greatly appreciated.

The approved ("-A") version of this report has been verified by the NRC staff to include NRC staff's safety evaluation of the transmitted technical report, revised to incorporate responses to NRC staff's requests for additional information (RAIs) and a comment/resolution table. This version is acceptable for use.

NOTICE

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Fields, Leslie

To: RICHTER, Mark; Earl Mayhorn (EMayhorn@ameren.com) (EMayhorn@ameren.com)
Cc: Morey, Dennis; Diaz-Castillo, Yamir; Park, Dong; Kavanagh, Kerri
Subject: NRC Transmittal of the Final SE for NEI 14-05A, Revision 1

February 19, 2021

Mark A. Richter, Ph.D.
Senior Project Manager,
Nuclear Energy Institute
1201 F St NW, Suite 1100
Washington, DC 20004

Dear Mr. Richter,

By letter dated February 20, 2020 (Agencywide Documents Access and Management System Accession No. (ADAMS No.) ML20034F042), the Nuclear Energy Institute (NEI) submitted Revision 1 of Technical Report (TR) NEI 14-05 A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," to the U.S. Nuclear Regulatory Commission (NRC) for NRC staff review and approval. By email dated October 31, 2020, the NRC staff issued its draft safety evaluation (SE) (ADAMS Nos. ML20300A454 and ML20300A011).

NEI provided comments on the draft SE by email dated November 16, 2020. Nonproprietary copies of the comments are available in ADAMS.

The NRC staff concludes that the TR continues to provide an acceptable approach for licensees and suppliers subject to the quality assurance (QA) requirements of Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 to the extent specified and under the limitations delineated in the TR and in the enclosed SE. The final SE defines the basis for our acceptance of the TR.

Our acceptance applies only to material provided in the subject TR. When a licensee uses NEI 14-05 A, Revision 1, the NRC staff would not need to perform any additional review for those referencing the license amendment for the QA program change. License amendment requests that deviate from this TR will be subject to a plant specific review in accordance with applicable review standards.

In accordance with the guidance provided on the NRC website, we request that NEI publish an accepted version of the TR, within three months of receipt of the date of this email. The accepted version shall incorporate this email and the enclosed SE after the title page.

Both this email and the final SE have been placed in ADAMS (under Nos. ML20322A454 and ML20322A019), made Official Agency Records, and declared publicly available.

Also, the accepted versions must contain historical review information, including NRC requests for additional information (RAI) questions and responses. The accepted versions shall include a "-A" (designating approved) following the TR identification symbol.

As an alternative to including the RAI questions and RAI responses behind the title page, if changes to the TR provided to the NRC staff to support the resolution of RAI responses, and the NRC staff reviewed and approved those changes as described in the RAI responses, there are two ways that the accepted version can capture the RAIs:

1. The RAI questions and responses can be included as an Appendix to the accepted version.
2. The RAI questions and responses can be captured in the form of a table (inserted after the final SE) which summarizes the changes as shown in the accepted version of the TR. The table should reference the specific RAI questions and RAI responses which resulted in any changes, as shown in the accepted version of the TR.

If future changes to the NRC's regulatory requirements affect the acceptability of this TR, NEI will be expected to revise the TR appropriately. Licensees referencing this TR would be expected to justify its continued applicability or evaluate their plant using the revised TR.

If you have any questions, please contact the Project Manager for the review, Leslie Fields, at 301-415-1186 or via electronic mail at leslie.fields@nrc.gov.

/RA/

Sincerely,
Dennis Morey, Chief
Licensing Processes Branch
Division of Operating Reactor Licensing
Office of Nuclear Reactor Regulation

Docket No. 99902038



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

FINAL SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION
FOR THE NUCLEAR ENERGY INSTITUTE TECHNICAL REPORT 14-05A,
"GUIDELINES FOR THE USE OF ACCREDITATION IN LIEU OF COMMERCIAL
GRADE SURVEYS FOR PROCUREMENT OF LABORATORY
CALIBRATION AND TEST SERVICES," REVISION 1
EPID L-2020-TOP-0011

1.0 INTRODUCTION

By letter dated February 20, 2020 (Reference (Ref.) 1), the Nuclear Energy Institute (NEI) submitted Revision 1 to Technical Report (TR) NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," for U.S. Nuclear Regulatory Commission (NRC) staff review and endorsement. Revision 1 of NEI 14-05A provides an updated approach for licensees and suppliers of basic components for using laboratory accreditation by Accreditation Bodies (ABs) that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) (hereby after referred to as the ILAC accreditation process) in lieu of performing commercial-grade surveys for procurement of calibration and testing services. This method of qualifying the calibration and testing supplier and accepting its calibration and testing services would be applied only to dedication of commercial-grade calibration and testing services as defined by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance."

2.0 BACKGROUND

In a letter dated August 28, 2014 (Ref. 2), NEI submitted Revision 1 to NEI 14-05, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," for NRC staff review and endorsement. In its safety evaluation (SE) dated February 9, 2015 (Ref. 3), the NRC staff determined that Revision 1 of NEI 14-05 provided an acceptable approach for licensees and suppliers subject to the quality assurance (QA) requirements of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," for using laboratory accreditation by ABs that are signatories to the

ILAC MRA in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.

By letter dated April 1, 2016 (Ref. 4), the NRC staff approved a request to change the "Operating Quality Assurance Manual" for Callaway Plant, Unit 1, pursuant to 10 CFR 50.54(a) to incorporate the QA alternative of using the ILAC accreditation process in lieu of performing a commercial-grade survey. With this approval, other licensees could use the ILAC accreditation process in lieu of performing commercial-grade surveys for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA provided the bases of the NRC approval are applicable to the licensee's facility pursuant to the requirements of 10 CFR 50.54(a)(3)(ii).

In a letter dated October 1, 2018 (Ref. 5), NEI requested the NRC to recognize the 2017 edition of the International Standard Organization /International Electrotechnical Commission standard No. 17025 (2017 edition ISO/IEC 17025), "General Requirements for the Competence of Testing and Calibration Laboratories," for use during the three-year transition period that began on November 30, 2017, and is set to expire on November 30, 2020. This time period was established by ISO to allow accredited laboratories to transition from the 2005 to the 2017 edition of ISO/IEC 17025. Subsequently, in a letter responding to NEI's request dated April 16, 2019 (Ref. 6), the NRC concluded that the 2017 edition of ISO/IEC 17025 maintains the same technical and quality requirements as the 2005 edition of ISO/IEC 17025. Therefore, licensees and suppliers of basic components may procure calibration and/or testing services from domestic and international laboratories accredited to the 2017 edition of ISO/IEC 17025 in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process during the transition period established by ISO, with the expectation the industry would seek recognition of the 2017 edition of ISO/IEC 17025 beyond the transition period through a revision of NEI 14-05A.

By electronic mail (e-mail) dated May 1, 2020 (Ref. 7), the NRC transmitted a request for additional information (RAI) to complete its review of Revision 1 of NEI 14-05A. In a letter dated May 13, 2020 (Ref. 8), NEI submitted its response to the RAI and an update to Revision 1 of NEI 14-05A (Ref. 9), which incorporated NEI's response to the NRC staff's RAI. By e-mail dated July 6, 2020 (Ref. 10), the NRC transmitted a second round of RAIs to address issues related to the recent Coronavirus Disease 2019 (COVID-19) pandemic. In a letter dated September 11, 2020 (Ref. 11), NEI submitted its response to the RAIs and an update to Revision 1 of NEI 14-05A (Ref. 12), which incorporated NEI's responses to the NRC staff's RAIs.

Revision 1 of NEI 14-05A was updated to recognize the 2017 edition of ISO/IEC 17025 as the basis for the ILAC accreditation process and to address other minor editorial changes, clarifications, and adjustments based on operating experience identified subsequent to the NRC's initial endorsement in February 2015.

3.0 TECHNICAL EVALUATION

3.1. Limitations of Use

Section 3.4, "Limitations of Use," in Revision 1 of NEI 14-05A clarifies that the guidance for the use of the ILAC accreditation process was developed as part of the commercial-grade dedication process for laboratory calibration and testing services by licensees and suppliers of basic components. The NRC staff recognizes that the use of the 2017 edition ISO/IEC 17025 for procurement of calibration and testing services is not limited to licensees and suppliers of basic components. However, the NRC's approval for using the ILAC accreditation process in lieu of performing commercial-grade surveys, and the acceptance of inspection and tests results to determine conformance with the applicable requirements, can only be implemented by a supplier who has a QA program that meets the applicable requirements of Appendix B to 10 CFR Part 50. When commercial-grade surveys are utilized as an acceptance method, the commercial-grade survey report must document the commercial supplier's control over the identified critical characteristics and the associated quality controls that affect the critical characteristics such as calibration of measuring and test equipment. Subsequent use of the ILAC accreditation process by commercial sub-suppliers is inadequate and should be adequately controlled irrespective of the fact that the commercial sub-suppliers are implementing the same QA program based on ISO 17025. The commercial-grade survey report must document the acceptability of the commercial sub-supplier's control over calibration and not merely state the commercial sub-supplier uses accredited calibration or testing service providers based on the accreditation to the 2017 edition of ISO/IEC 17025. Commercial-grade survey reports should address the selection and approval of supplier and the overall procurement controls as applicable for such suppliers.

Section 3.4 also describes the use of the ILAC accreditation process for nondestructive examination (NDE) or nondestructive testing (NDT) since these services can potentially be dedicated. For the purposes of this SE, the terms NDE and NDT are considered equivalent and can be used interchangeably. The Electric Power Research Institute (EPRI) TR No. 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications," dated September 2014 (Ref. 13), states that the procurement of NDE services performed on safety-related equipment may be dedicated. Although EPRI 3002002982 is endorsed by Regulatory Guide (RG) 1.164, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants," Revision 0, dated June 2017 (Ref. 14), the NRC's recognition of the ILAC accreditation process did not intend to include the commercial-grade dedication of NDE services based on a laboratory's accreditation to the 2017 edition of ISO/IEC 17025. There are specific personnel qualification and certification requirements for personnel performing safety-related NDE activities for the nuclear industry that are not addressed by the ILAC accreditation process. Therefore, the ILAC accreditation process cannot be used as part of the commercial-grade dedication process of NDE services in lieu of performing a commercial-grade survey. This is applicable to both American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (B&PV) Code and non-ASME B&PV Code safety-related applications. It should be noted that use of the ILAC accreditation process for NDE services required by the ASME B&PV Code is also prohibited by the ASME B&PV Code.

3.2 Performing and Documenting a Technical Evaluation for the Calibration and/or Testing Services

As part of the commercial-grade dedication process, licensees and suppliers of basic components should perform and document a technical evaluation to ensure that the correct technical requirements are specified in the procurement documents. The NRC's recognition of the ILAC accreditation process allows licensees and suppliers of basic components to use this accreditation in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process for calibration and testing services. As such, the NRC staff expects licensees and suppliers of basic components to follow the commercial-grade dedication process, which includes performing and documenting a technical evaluation for the calibration and/or testing services being procured.

Attachment 1 and Attachment 2 to Revision 1 of NEI 14-05A include acceptable examples of a technical evaluation for calibration services and testing services, respectively. These technical evaluations address measuring and calibration services from commercial calibration service providers and laboratory testing services from commercial testing service providers including ISO/IEC 17025:2005 and ISO/IEC 17025:2017 accredited laboratories and non-accredited service providers.

3.3 New Conditions: Subcontracting of Services and Remote Accreditation Assessments

3.3.1 Subcontracting of Services

The use of subcontracting services is allowed by the 2017 edition of ISO/IEC 17025. At the time the NRC staff recognized the ILAC accreditation process, none of the conditions imposed prohibited the use of subcontractors to perform any calibration and/or testing work. However, in order to ensure that the calibration and/or testing work is performed by an ILAC accredited laboratory and reduce the chance of misuse of the ILAC accreditation process and not receive an accredited service, the procurement documents must prohibit the accredited calibration or testing laboratory from subcontracting the service being procured. The procurement document for accredited services must be submitted directly to the entity performing the calibration or testing. It should be noted when using the ILAC accreditation process under the ASME B&PV Code, subcontracting of services is also prohibited.

3.3.2 Remote Accreditation Assessments

The NRC's recognition of the ILAC accreditation process allows licensees and suppliers of basic components to take credit for the ILAC accreditation process in lieu of performing an on-site commercial-grade survey as part of the commercial-grade dedication process of calibration and testing services. In its initial recognition of the ILAC accreditation process, the NRC staff determined that as part of the on-site renewal assessments performed by the ABs, the critical characteristics for calibration and testing services would be verified as part of the on-site renewal assessment. Due to the travel restrictions caused by the COVID-19 pandemic, ABs are performing remote accreditation assessments. While use of remote accreditation assessments were determined by the nuclear industry to be acceptable during extenuating circumstances, it is necessary to impose a limitation on the use of remote assessment for laboratories performing calibrations and testing for licensees and suppliers of basic

components. Accredited calibration or testing services performed on behalf of licensees and suppliers of basic components cannot be accepted from laboratories who have not undergone an on-site accreditation assessment within the past 48 months of the date of services. Such laboratories cannot be used by licensees and suppliers of basic components if their accreditation is based on consecutive remote accreditation assessments. Due to the travel restrictions caused by the COVID-19 pandemic, the NRC approved an overall 25 percent extension (9 months) prior to the end of the 90-day grace period for triennial audits or surveys during periods where performance of such activities is not feasible as a result of extenuating circumstances. With the added assurance that remote renewal accreditations are 24 months, the NRC staff concludes that there is reasonable assurance that the on-site accreditation assessments within 48 months meet the requirement with respect to performing commercial-grade surveys as part of the commercial-grade dedication process.

3.4 Implementation of the ILAC Accreditation Process in Lieu of a Commercial-Grade Survey

The following are the actions and steps that are necessary for a licensee and/or a supplier of basic components to accept accreditation of domestic and international calibration and test laboratory services by ILAC MRA signatories in lieu of performing a commercial-grade survey as part of the commercial-grade dedication process:

- 1) The method to use accreditation by an ILAC MRA signatory in lieu of a commercial-grade survey (alternative method) is documented in the licensee and/or supplier of basic components' QA program.
- 2) The method the licensee and/or supplier of basic components needs to follow, and document in their QA program, consists of:
 1. A documented review of the laboratory's accreditation is performed and includes a verification of the following:
 - a. The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories."
 - b. For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
 - c. For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.
 - d. The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.

2. The purchase documents require that:
 - a. The service must be provided in accordance with their accredited ISO/IEC-17025:2017 program and scope of accreditation.
 - b. As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance (for calibration services only).
 - c. The equipment/standards used to perform the calibration must be identified in the certificate of calibration (for calibration services only).
 - d. Subcontracting of these accredited services is prohibited.
 - e. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
 - f. Performance of the services listed on this order is contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the AB within the past 48 months.
 - g. Any additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.
3. It is validated, at receipt inspection, that the laboratory's documentation certifies that:
 - a. The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2017 program, and has been performed within their scope of accreditation, and
 - b. The purchase order's requirements are met.

4.0 APPLICABILITY

Due to the travel restrictions resulting from the COVID-19 pandemic, ILAC extended the transition period originally scheduled to end on November 30, 2020, to June 1, 2021. During the transition period between the issuance of this SE endorsing Revision 1 of NEI 14-05A through June 1, 2021, the NRC staff determined that the 2005 and 2017 editions of ISO/IEC 17025, as well as Revision 0 and Revision 1 of NEI 14-05A, are acceptable for use. Starting on June 2, 2021, after the transition period has ended, Revision 0 of NEI 14-05A will become superseded by Revision 1 of NEI 14-05A and licensees and suppliers of basic components using the ILAC accreditation process in lieu of performing a commercial-grade survey for calibration and testing services will have to start implementing Revision 1 of NEI 14-05A. However, if a licensee or a supplier of basic components incorporates Revision 1

of NEI 14-05A into its QA program before the transition period ends on June 1, 2021, the new conditions as described in Revision 1 of NEI 14-05A will go into effect.

For licensees, the use of the 2017 edition of ISO/IEC 17025 as part of the ILAC accreditation process in lieu of performing a commercial-grade survey represents a QA alternative to the previously accepted QA program. As such, licensees may adopt the QA alternative of using the 2017 edition of ISO/IEC 17025 provided that the bases of the NRC's approval are applicable to the licensee's facility pursuant to the requirements of 10 CFR 50.54(a)(3)(ii).

After June 1, 2021, the 2005 edition of ISO/IEC 17025 will become invalid and only accreditation to the 2017 edition of ISO/IEC 17025 can be achieved and recognized under the ILAC MRA process. Therefore, this SE recognizes accreditation to the 2005 edition of ISO/IEC 17025 through June 1, 2021.

5.0 CONCLUSION

On the basis of its review, the NRC staff concludes that Revision 1 of NEI 14-05A continues to provide an acceptable approach for licensees and suppliers subject to the QA requirements of Appendix B to 10 CFR Part 50 for using laboratory accreditation by ABs that are signatories to the ILAC MRA in lieu of performing commercial-grade surveys as part of the commercial-grade dedication process for procurement of calibration and testing services performed by domestic and international laboratories accredited by signatories to the ILAC MRA.

6.0 REFERENCES

1. Letter from Mr. Mark A. Richter, Senior Project Manager, Used Fuel and Decommissioning Programs, NEI, to Ms. Kerri A. Kavanagh, Chief, Quality Assurance and Vendor Inspection Branch, "Submittal of NEI 14-05A, Revision 1, 'Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,'" dated February 20, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20054C066).
2. Letter from Mr. Marcus R. Nichol, Senior Project Manager, Quality Issues and Licensing Actions, NEI, to Mr. Joseph Colaccino, Chief, New Reactor Rulemaking and Guidance Branch, Division of Advanced Reactors and Rulemaking, Office of New Reactors, "Submittal of NEI 14-05, Revision 1, Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," dated August 28, 2014 (ADAMS Accession No. ML14245A391).
3. Letter from Mr. Joseph Colaccino, Chief, New Reactor Rulemaking and Guidance Branch, Division of Advanced Reactors and Rulemaking, Office of New Reactors, to Mr. Marcus R. Nichol, Senior Project Manager Quality Issues and Licensing Actions, Nuclear Energy Institute, "Final Safety Evaluation for Technical Report NEI 14-05, 'Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,' Revision 1," dated February 9, 2015 (ADAMS Accession No. ML14322A535).

4. Letter from Mr. L. John Klos, Project Manager, Plant Licensing Branch IV-1 Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation to Mr. Fadi Diya, Senior Vice President and Chief Nuclear Officer, Union Electric Company, "Callaway Plant, Unit 1 – Operating Quality Assurance Manual Revision 31, Change Notice 15-002," dated April 1, 2016 (ADAMS Accession No. ML16089A167).
5. Letter from Mr. Mark A. Richter, Senior Project Manager, Used Fuel and Decommissioning Programs, NEI, to Ms. Kerri A. Kavanagh, Chief, Quality Assurance Vendor Inspection Branches 1 & 2, "Endorsement of ISO/IEC 17025: 2017, 'General Requirements for the Competence of Testing and Calibration Laboratories,'" dated October 1, 2018 (ADAMS Accession No. ML18275A121).
6. Letter from Ms. Jennivine Rankin, Chief, Licensing Branch 2, Division of Licensing, Siting, and Environmental Reviews, Office of New Reactors to Mr. Mark A. Richter, Senior Project Manager, Used Fuel and Decommissioning Programs, Nuclear Energy Institute, "Provisional Recognition of the International Standard Organization/International Electrotechnical Commission Standard No. 17025, 'General Requirements for the Competence of Testing and Calibration Laboratories,'" 2017 Edition," dated April 16, 2019 (ADAMS Accession No. ML19056A451).
7. E-mail transmittal from Leslie Fields, Senior Project Manager, Licensing Processes Branch, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation to Mr. Mark A. Richter, Senior Project Manager, Used Fuel and Decommissioning Programs, NEI, "Request for Additional Information for NEI 14-05A Revision 1," dated May 1, 2020 (ADAMS Accession No. ML20121A319).
8. Letter from Mr. Mark A. Richter, Senior Project Manager, Used Fuel and Decommissioning Programs, NEI, to Leslie Fields, Senior Project Manager, Licensing Processes Branch, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation, "Submittal of Response to Request for Additional Information (RAI) for NEI 14-05A, Revision 1, "Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services," dated May 13, 2020 (ADAMS Accession No. ML20135H214).
9. Revision 1 of NEI 14-05A, "Revision 1 of NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services," dated May 2020 (ADAMS Accession No. ML20135H229).
10. E-mail transmittal dated from Leslie Fields, Senior Project Manager, Licensing Processes Branch, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation to Mr. Mark A. Richter, Senior Project Manager, Used Fuel and Decommissioning Programs, NEI, "Request for Additional Information (RAI) for NEI 14-05A, Revision 1," dated July 6, 2020 (ADAMS Accession No. ML20184A288).
11. Letter from Mr. Mark A. Richter, Senior Project Manager, Used Fuel and Decommissioning Programs, NEI, to Leslie Fields, Senior Project Manager, Licensing Processes Branch, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation, "Submittal of Response to Request for Additional Information (RAI) for NEI 14-05A, Revision 1,

“Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services,” dated September 11, 2020 (ADAMS Accession No. ML20259C391).

12. Revision 1 of NEI 14-05A, “Guidelines for the Use of Accreditation in Lieu of Commercial-Grade Surveys for Procurement of Laboratory Calibration and Test Services,” dated September 2020 (ADAMS Accession No. ML20259B731).
13. EPRI TR 3002002982, “Plant Engineering: Guideline of Commercial-Grade Items in Nuclear Safety-Related Applications,” Revision 1, September 2014 (ADAMS Accession No. ML181999A161).
14. RG 1.164, “Dedication of Commercial-Grade Items for Use in Nuclear Power Plants,” Revision 0, dated June 2017 (ADAMS Accession No. ML17041A206).

Attachment: Comment Resolution Table

Principal Contributors: Yamir Diaz-Castillo, NRR/DRO
Dong Park, NRR/DRO

Date: November 23, 2020

**TECHNICAL REPORT NEI 14-05A, REVISION 1
COMMENT RESOLUTION TABLE**

Comment Number	Text Location in the DSE		Comment Type (Clarification, Editorial, Accuracy, Proprietary)	NEI Suggested Revision	NRC Response
	Page	Line			
1	2	40-44	Accuracy	Please replace the current wording in Lines 40-44 with the following: "Revision 1 of NEI 14-05A was updated to recognize ISO/IEC 17025:2017 as the basis for the ILAC process and to address other minor editorial changes, clarifications, and adjustments based on operating experience identified subsequent to the NRC's initial endorsement in February 2015."	NRC staff finds the comment acceptable and the revisions have been incorporated with a few minor edits as shown below: "Revision 1 of NEI 14-05A was updated to recognize the 2017 edition of ISO/IEC 17025 as the basis for the ILAC accreditation process and to address other minor editorial changes, clarifications, and adjustments based on operating experience identified subsequent to the NRC's initial endorsement in February 2015."

FOREWORD

The purpose of this guidance is to describe an acceptable approach for using laboratory accreditation by Accreditation Bodies (ABs) that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) (referred to as the ILAC process) in lieu of commercial grade surveys as part of commercial grade dedication. The scope includes commercially procured calibration and test services performed by domestic and international laboratories accredited by ILAC signatories. The approach also includes continued oversight of the ILAC process by the nuclear industry to verify that the ILAC process continues to be an equivalent alternative to a commercial grade survey. In developing this approach, NEI's ILAC Task Force observed peer evaluations of international Accreditation Bodies, assessments of calibration and testing laboratories, training for peer evaluators, and ILAC accreditation meetings. Based upon these observations, it was concluded that the ILAC process is essentially equivalent to the U.S. Nuclear Regulatory Commission (NRC) accepted practices for performing commercial grade surveys.

NRC's endorsement of this guidance expands NRC's recognition of the ILAC process first documented in a Safety Evaluation Report (SER) on an Arizona Public Service (APS) request. NRC's earlier recognition was limited to laboratory calibration services accredited by specific U.S. Accreditation Bodies. With endorsement by the NRC, licensees and suppliers may use this guidance to credit accreditation by ILAC signatories, both domestic and international, in the commercial grade dedication of laboratory calibration and test services.

Summary of Revision 1 changes

The NRC endorsed the process described in NEI 14-05A Rev 0 as reflected in the Final Safety Evaluation Report¹ dated February 9, 2015.

Prior to a licensee implementing the methodology outlined in NEI 14-05A, Revision 0, the NRC required a licensee to submit a revision to its Operating Quality Assurance Program (OQAP) for NRC acceptance in accordance with 10 CFR 50.54(a)(4) since implementation of NEI 14-05A represented a reduction in commitment. Ameren (AUE) revised the Ameren Callaway Unit 1 OQAP adopting NEI 14-05A and submitted it to the NRC for approval in October 2015. The NRC issued a Final Safety Evaluation Report on April 1, 2016 approving Ameren's implementation of the ILAC process in accordance with NEI 14-05A, revision 0. Other licensees subsequently revised their Quality Assurance Programs to implement the ILAC process based on the NRC's Safety Evaluation Report (SER) issued to AUE.

¹ [ML14322A535](#)

On November 30, 2017, the International Standards Organization (ISO) released ISO/IEC 17025:2017. Since the above-mentioned SERs only recognized ISO/IEC 17025:2005, the NEI ILAC Taskforce performed a gap analysis between ISO/IEC 17025:2005 and ISO/IEC 17025:2017 and concluded the newer version (2017) of the standard is equivalent to the older version (2005) which was previously recognized by the NRC. ISO/IEC 17025:2017 included some updates and enhancements but did not represent a reduction in commitment to quality. Based on this conclusion, the nuclear industry requested the NRC's recognition of ISO/IEC 17025:2017 during the ISO-designated three-year transition period (that began on November 30, 2017) in a letter dated October 1, 2018. On April 16, 2019, the NRC issued a letter provisionally recognizing ISO/IEC 17025:2017 during the transition period with the expectation that the industry would submit a revision to NEI 14-05A requesting NRC recognition of ISO/IEC 17025:2017 beyond the transition period which was originally scheduled to end on November 30, 2020. However, due to travel restriction resulting from the COVID-19 Pandemic, ILAC extended the transition period to June 1, 2021. In addition to revising NEI 14-05A to recognize ISO/IEC 17025:2017 as the basis of the ILAC process, the revision was expected to address other minor editorial changes, clarifications, and adjustments based on operating experience subsequent to the NRC endorsement in February 2015. The changes represented in NEI 14-05A, Revision 1 are summarized as follows:

- References to ISO/IEC 17025:2005 have been replaced with references to ISO/IEC 17025:2017, with the understanding that ISO/IEC 17025:2005 will remain valid through June 1, 2021.
- Clarifications on limits of use have been added to indicate the ILAC process is not intended to be utilized for the commercial grade dedication of Nondestructive Examination (NDE) services.
- Subcontracting of accredited services is prohibited. The laboratory that is contracted to perform the required accredited calibration or testing must perform the service and cannot subcontract the services to another accredited laboratory.
- The ILAC process is intended for use by licensees and suppliers of basic components as a part of the commercial grade dedication process and must be used in conjunction with other NRC-endorsed commercial grade dedication guidance such as EPRI TR3002002982. This includes clarifying that a commercial grade dedication technical evaluation is required as a part of the ILAC process to document the critical characteristics and acceptance method for calibration and testing services.
- The NRC's endorsement of the use of accreditation to ISO/IEC 17025:2017 by Accreditation Bodies (ABs) that are signatories to the ILAC MRA in lieu of performing a commercial grade survey for the acceptance of calibration and testing services was

largely based on ABs performing on-site accreditation assessments at laboratories. Due to travel restrictions caused by the COVID-19 pandemic, ABs are performing remote accreditation assessments. A limitation has been placed on the use of remote accreditation assessments to maintain accreditation. Accredited testing or calibration services performed on behalf of licensees and suppliers of basic components cannot be accepted from laboratories who have not undergone an on-site accreditation assessment within the past 48 months of the date of services. In effect, this means that such laboratories cannot maintain accreditation based on consecutive remote accreditation assessments.

- Sample technical evaluations for both calibration and testing services have been included as attachments to NEI 14-05A, Rev. 1.

These changes represent clarifications and conservative adjustments and the ILAC process that was endorsed by the NRC in NEI 14-05A, Revision 0 remains fundamentally unchanged.

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Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services

1 INTRODUCTION

1.1 PURPOSE

The purpose of this guidance is to provide an acceptable approach for procuring commercial grade calibration and testing services by laboratories accredited by International Laboratory Accreditation Cooperation (ILAC) signatories. Access to internationally (including both domestic and international) accredited calibration and testing services benefits licensees and their suppliers through reduced cost, expanded access to services, improved quality of services, and improved regulatory confidence.

This approach takes advantage of the internationally recognized standards and accreditation process when qualifying suppliers to perform calibration and test services for the nuclear industry. Purchasers (licensees and suppliers of basic components) that procure commercial grade calibration or testing laboratory services are able to rely on laboratory accreditation by Accreditation Bodies (ABs) that are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) (referred to as the ILAC process) in lieu of commercial grade surveys to provide the necessary evidence of compliance to qualify calibration or test suppliers under a Commercial Grade Dedication process. The net result will be a substantial reduction in duplication of effort for qualifying these suppliers across the industry, while ensuring that the applicable requirements for commercial grade dedication continue to be met.

1.2 REGULATORY BASIS

Items and services used in safety related applications at US commercial nuclear power plants are designated as basic components and are required to be provided in accordance with 10 CFR Part 50, Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.” 10 CFR Part 50, Appendix B, includes requirements for calibration and testing associated with basic components.

It is not always possible or practical to procure items and services directly from suppliers that implement quality assurance programs that meet 10 CFR Part 50, Appendix B. Therefore, the NRC established requirements in 10 CFR Part 21, “Reporting of Defects and Noncompliance,” that permit the use of commercial grade items and services in nuclear safety related applications through a commercial grade dedication process.

Although the suppliers of commercial grade items and services are not required to comply with 10 CFR Part 50, Appendix B requirements, the commercial grade dedication activities must be performed under a Quality Assurance Program that meets the requirements of 10 CFR Part 50, Appendix B.

The process for accepting items and services for use as basic components from commercial suppliers is known as Commercial Grade Dedication (CGD or Dedication). An acceptable approach for dedicating commercial grade items includes the need to verify the critical characteristics for commercial grade items and services and a Commercial Grade Survey is one of four acceptable methods to perform this verification. This approach is described in EPRI TR03002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications," Revision 1 to EPRI NP-5652 and TR-102260 or other equivalent EPRI guidance².

The Nuclear Procurement Issues Corporation (NUPIC) is an association of U.S. nuclear power plant operators and a number of international nuclear power plant operators with the mission to improve supplier quality assurance and oversight processes through cooperative efforts. NUPIC has established processes and checklists to perform commercial grade surveys that meet the applicable requirements of 10 CFR Part 21 and 10 CFR Part 50, Appendix B, and associated guidance.

This guidance document describes a method for using the ILAC process in the procurement of commercial grade laboratory calibration and test services and dedication of these laboratory services in compliance with 10 CFR Part 21 and 10 CFR Part 50, Appendix B. This guidance is applicable to dedicating entities subject to the quality assurance requirements of 10 CFR Part 50, Appendix B 10 CFR Part 52, 10 CFR Part 71 and 10 CFR Part 72 licensees and suppliers. Only such licensees and suppliers should use the methodology described herein in lieu of performing a commercial grade survey during the dedication of commercial calibration and testing services.

1.3 ACCEPTANCE OF ACCREDITATION BY ILAC SIGNATORIES IN LIEU OF COMMERCIAL GRADE SURVEYS

Calibration and testing services provided by internationally accredited laboratories under the ILAC process are commercial grade services. The guidance within describes an approach to rely on the accreditation by an ILAC signatory in lieu of commercial grade surveys in the commercial grade dedication process. The approach used to develop this

² EPRI guidance on commercial grade dedication titled "Guideline for the Acceptance of Commercial Grade Items in Nuclear Safety-Related Applications," Revision 1, 3002002982, has been used which supersedes EPRI-NP5652 and EPRI TR-102260. The approach in EPRI TR 3002002982 has been endorsed in NRC Regulatory Guide 1.164. The user of this guidance document on the use of the ILAC process in lieu of a commercial grade survey should use the NRC endorsed guidance available at the time the dedication activities are performed.

guidance was to compare the ILAC process with NRC accepted practices for commercial grade surveys to evaluate their equivalence and determine whether any additional actions are necessary to address differences between them. Section 2 describes the ILAC processes and Section 6 provides the U.S. nuclear industry's evaluation of ILAC process and comparison with NRC accepted practices. Section 5 describes the approach for the U.S. nuclear industry to provide continued oversight of the ILAC process in order to confirm that the ILAC process can continue to be used in lieu of commercial grade surveys for the purpose of commercial grade dedication, as described in this guidance.

Based upon the conclusion that the ILAC process is essentially equivalent to NUPIC practices, it has been determined that the accreditation by ILAC signatories can be used, with the inclusion of a few requirements in the procurement documents, in lieu of a commercial grade survey to comply with the applicable requirements of 10 CFR Part 50, Appendix B and 10 CFR Part 21, and associated guidance. It should be noted that commercial grade surveys are required to be performed at the supplier/laboratory site. Due to travel restrictions resulting from the COVID-19 Pandemic, ABs are employing remote accreditation assessments. As a result, this document imposes a limitation on the use of remote assessment accreditation. Laboratories performing work for licensees and suppliers of basic components based on the laboratory's accreditation to ISO/IEC 17025:2017 cannot maintain their accreditation based on consecutive remote accreditation assessments. This limitation helps maintain the equivalence of the accreditation process to the nuclear industry's commercial grade survey process.

Section 3 describes how purchasers of international calibration and testing laboratory services should use the accreditation by ILAC signatories as part of their commercial grade Dedication activities. It is noted that this guidance should be used in conjunction with guidance on commercial grade dedication. Therefore, the ILAC process is intended for use in lieu of commercial grade surveys by licensees and suppliers of basic components and licensees and suppliers implementing 10 CFR Part 71 and 10 CFR Part 72 programs. In addition, Section 4 describes information that purchasers should ensure is included in their Quality Assurance Programs.

The following are the actions and steps that are necessary in order for a purchaser to accept accreditation of international calibration and test laboratory services by ILAC MRA signatories in lieu of performing a commercial grade survey as part of commercial grade dedication. Additional detail on performing these steps is discussed in subsequent sections of this guidance.

- 1) The method to use accreditation by an ILAC MRA signatory in lieu of a commercial grade survey (alternative method) is documented in the purchaser's QA program.

- 2) The method the purchaser needs to follow, and document in their QA program, consists of:
 1. A documented review of the supplier's accreditation is performed and includes a verification of the following:
 - a. The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories."
 - b. For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
 - c. For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.
 - d. The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.
 2. The purchase documents require that:
 - a. The service must be provided in accordance with their accredited ISO/IEC-17025:2017 program and scope of accreditation.
 - b. As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance. *(for calibration services only)*
 - c. The equipment/standards used to perform the calibration must be identified in the certificate of calibration. *(for calibration services only)*
 - d. Subcontracting of these accredited services is prohibited.
 - e. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
 - f. Performance of the services listed on this order is contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the Accreditation Body within the past 48 months.
 - g. Any additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.
 3. It is validated, at receipt inspection, that the laboratory's documentation certifies that:

- a. The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2017 program, and has been performed within their scope of accreditation, and
- b. The purchase order's requirements are met.

ISO/IEC 17025:2017 was released on November 30, 2017. During the transition period, both ISO/IEC 17025:2005 and ISO/IEC 17025:2017 are valid. Originally, ILAC assigned a three-year transition period ending on November 30, 2020. However, in June 2020, ILAC extended the end of the transition period from November 30, 2020 to June 1, 2021 due to travel restrictions caused by the global coronavirus disease 2019 (COVID-19) outbreak. This additional time will allow all laboratories the time needed to complete the transition. After June 1, 2021, ISO/IEC 17025:2005 will become invalid and only accreditation to ISO/IEC 17025:2017 can be achieved and recognized under the ILAC MRA process. Therefore, this document recognizes accreditation to ISO/IEC 17025:2005 through June 1, 2021.

1.4 ACRONYMS

A2LA – American Association for Laboratory Accreditation

AB – Accreditation Body

APLAC – Asia Pacific Laboratory Accreditation Cooperation

CAB – Conformity Assessment Body

CFR – Code of Federal Regulations

CGD – Commercial Grade Dedication

EA – European Cooperation for Accreditation

EPRI – Electric Power Research Institute

GL – Generic Letter

IAAC – Inter American Accreditation Cooperation

IAF – International Accreditation Forum

IEC – International Electrotechnical Commission

ILAC – International Laboratory Accreditation Cooperation

ISO – International Organization for Standardization

JAB – Japan Accreditation Board

JIG – Joint Inspection Group
M&TE – Measuring and Test Equipment
MRA – Mutual Recognition Arrangement
NDT – Non-Destructive Testing
NDE – Non-Destructive Examination
NEI – Nuclear Energy Institute
NIST – National Institute of Standards and Technology
NRC – Nuclear Regulatory Commission
NUPIC – Nuclear Procurement Issues Corporation
QA – Quality Assurance
QC – Quality Control

2 INTERNATIONAL LABORATORY ACCREDITATION COOPERATION (ILAC)

2.1 DESCRIPTION OF THE INTERNATIONAL LABORATORY ACCREDITATION COOPERATION

ILAC was formalized as a cooperative agreement in 1996 by a memorandum of understanding signed by 44 national bodies. In 2000, 36 laboratory accreditation bodies, (ILAC full members) signed a Mutual Recognition Arrangement (MRA or Arrangement) to promote the acceptance of accredited technical test and calibration data worldwide. The signatories had been evaluated by their peers (against the acceptance criteria of the then relevant ISO/IEC requirements) and demonstrated that they met ILAC criteria for competence. The current requirements for laboratories are in ISO/IEC 17025:2017, "General requirements for the competence of testing and calibration laboratories." Periodic reevaluations of ILAC signatories are conducted to maintain ILAC recognition. ILAC MRA documentation, including requirements for evaluation of accrediting bodies, is publicly available on the ILAC website.

The key to the Arrangement is the developing global network of accredited laboratories and inspection bodies that are assessed and recognized as being competent by ILAC Arrangement signatory accreditation bodies (ABs). The signatories have, in turn, been evaluated by their peers (against the requirements of ISO/IEC-17011:2017) and shown to meet ILAC's criteria for competence.

ILAC has several membership levels as described below:

Full Members – Full members are also known as ILAC MRA signatories. Each accreditation body that is a signatory to the MRA must maintain conformance with ISO/IEC-17011:2017 and other ILAC guidance and requirements, and ensure that all its accredited labs comply with the relevant international standard (i.e., ISO/IEC-17025:2017 for calibration and testing laboratories). The signatories have also been peer-reviewed and shown to meet ILAC’s criteria for competence. This guidance is only applicable for services provided by laboratories accredited by ILAC signatories (Full Members).

Associates – Accreditation bodies that are not signatories to the ILAC MRA, but which can provide evidence that they are operational and committed to comply with the requirements in relevant standards (e.g., ISO/IEC and ILAC) and obligations of the ILAC MRA, and are recognized in their economy as offering an accreditation service.

Affiliates – Accreditation bodies that are currently operating, being developed or intend to be developed, and declare their intention to operate their accreditation programs in compliance with the requirements in relevant standards (e.g., ISO/IEC and ILAC).

Stakeholders – Representative international, national and regional organizations having an interest in the work of ILAC, including associations of laboratories, regulatory authorities and trade organizations. NEI is a stakeholder member on behalf of the U.S. nuclear industry.

ILAC accomplishes its mission through the use of committees. The current listing of committees and their responsibilities are found on the ILAC website and are summarized as follows:

- **General Assembly** - is the primary body of ILAC and ensures that specific tasks are pursued in accordance with the objectives of ILAC. All members of ILAC are eligible to nominate one representative (delegate) to the General Assembly. The ILAC Chair is responsible for chairing meetings of the General Assembly.
- **Executive Committee** - Responsible for the day-to-day management of ILAC and its activities. The members of this committee consist of the Chair and Vice Chair of ILAC, the Chairs of those committees having strategic responsibilities for ILAC’s development, a representative of participating Regional Cooperation bodies, a representative of unaffiliated economies and other participants as determined by the General Assembly.

- **Arrangement Council** - is the decision-making body for determining signatory and recognition status under the ILAC Arrangement. The members of the Arrangement Council are delegates nominated by the Full and Associate members.
- **Arrangement Committee** - Responsible for harmonized implementation and continual improvement of the ILAC Arrangement. Deals with the approach of accreditation bodies to the assessment and accreditation of laboratories, the establishment of agreements between accreditation bodies and related policy areas.
- **Accreditation Committee** - Responsible for harmonization and improvement of accreditation practice at the international level. It is involved in the investigation of technical issues related to accreditation, and the development of technical documentation related to ILAC's work.
- **Laboratory Committee** - Provides a means of interaction and exchange of ideas between ILAC and the laboratory community.
- **Marketing and Communications Committee** - Responsible for internal and external marketing and communication issues. It is involved with the promotion of ILAC's objectives, and the publication of ILAC documents, newsletters and other information.
- **Arrangement Management Committee** - Responsible for the day-to-day management activities of the ILAC Arrangement on behalf of the Arrangement Council and provides advice on its further development and operation.
- **Joint Development Support Committee** - Responsible for representing the interests of developing countries and operates in conjunction with the International Accreditation Forum (IAF). This committee provides a forum for developing countries to present their needs and to work with ILAC and IAF on practical ways of addressing these needs.
- **Inspection Committee** - Responsible for the harmonization and improvement of accreditation practices for inspection activities at the international level. This Committee replaces the ILAC/IAF Joint Inspection Group (JIG). Members of ILAC and IAF with an interest in inspection activities participate in this Committee.
- **Financial Audit Committee** - Responsible for oversight of ILAC's financial accounting and reporting systems. Reviews and audits the finances of ILAC and

provides advice on financial matters to the ILAC Executive Committee and General Assembly.

- **Joint Meetings of the ILAC Executive and the IAF Executive** - Responsible for the stewardship of joint activities between ILAC and the International Accreditation Forum (IAF).

2.2 DESCRIPTION OF THE REGIONAL ORGANIZATIONS

In addition to the global ILAC organization, the accreditation bodies also belong to Regional Cooperation Bodies. Currently, the five regional cooperation bodies, whose Arrangements have been recognized by ILAC, are the Asian Pacific Accreditation Cooperation (APAC), African Accreditation Cooperation (AFRAC), Arab Accreditation Cooperation (ARAC), European Accreditation (EA), and Inter-American Accreditation Cooperation (IAAC).

There is close cooperation between ILAC and the regional cooperation bodies, and this cooperation is formalized in the ILAC MRA Policy Statement. Regional cooperation bodies evaluate and re-evaluate their member accreditation bodies. ILAC in turn recognizes the evaluation and re-evaluation of its member accreditation bodies carried out by the regional cooperation bodies. In addition, ILAC performs peer-evaluations of the regional cooperation bodies to establish and recognize their competence in management of the Arrangement.

2.3 DESCRIPTION OF ACCREDITATION BODIES

Accreditation Bodies (ABs) are organizations that assess and accredit Conformity Assessment Bodies (CABs). ABs assess and assure the competence of the CABs to perform conformity assessment services, including testing and calibration. ABs that are signatories to the ILAC MRA undergo peer evaluation to affirm their competence.

2.4 DESCRIPTION OF CONFORMITY ASSESSMENT BODIES

Conformity assessment bodies are organizations, including laboratories, that provide conformity assessment services for calibration and testing documented under specific, individual Scopes of Accreditation. CABs assess products, services and suppliers to assure conformity to specification and/or requirements under their Scopes of Accreditation. In this guidance document, the term laboratory is used to mean CAB.

3 USE OF LABORATORY SERVICES ACCREDITED BY ILAC MRA SIGNATORIES AS PART OF COMMERCIAL GRADE DEDICATION ACTIVITIES

The ILAC process is essentially equivalent to NRC accepted practices for commercial grade surveys that comply with the applicable requirements of 10 CFR Part 50, Appendix B and 10 CFR Part 21, and associated guidance. Therefore, accreditation by ILAC signatories can be used in lieu of a commercial grade survey as part of the commercial grade dedication process. This section describes how purchasers of internationally accredited calibration and testing laboratory services should use the ILAC process as part of their commercial grade dedication activities. It is noted that this guidance should be used in conjunction with EPRI guidance on commercial grade dedication (e.g., EPRI TR 3002002982).

3.1 OVERVIEW OF COMMERCIAL GRADE DEDICATION OF CALIBRATION AND TESTING LABORATORY SERVICES

The process of commercial grade dedication is widely utilized by purchasers to accept commercial grade calibration and testing services from commercial laboratories based on dedication of these services in accordance with the requirements of 10 CFR Part 50, Appendix B and 10 CFR Part 21, and associated guidance.

The commercial grade dedication process described in EPRI guidance includes the following activities:

- 1) Perform a technical evaluation to identify and document the safety function of the service;
- 2) Identify and document the credible failure modes for the service;
- 3) Identify and document the critical characteristics,
- 4) Identify and document the acceptance method(s), and
- 5) Implement the acceptance method(s).

The following are the four acceptable methods of verifying the adequacy of the critical characteristics for a commercial grade item and/or service (Activities 4 and 5):

Method 1 – Special Test/Inspection

Method 2 – Commercial Grade Survey³

Method 3 – Source Verification

Method 4 – Acceptance Item/Supplier Performance Record History

³ It is noted that Method 2 – Commercial Grade Survey – is widely accepted as the most practical acceptance method for calibration and testing laboratories that have well documented programs for controlling the critical characteristics identified by Purchasers.

Use of laboratory accreditation by ILAC signatories will be in lieu of commercial grade surveys as an acceptable alternative for Method 2. For purchasers that use internationally accredited calibration and testing laboratories, activities #1 through #3 of the commercial grade dedication process remain mostly the same. However, activities #4 and #5 for acceptance, would credit the accreditation by an ILAC signatory in lieu of a commercial grade survey (Method 2) as the means to verify the laboratory's control over the critical characteristics. Dedication of the contracted service is not complete until documentation has been reviewed to assure compliance with all purchase order requirements. The guidance in subsequent subsections describes how these activities are performed. Please note that the ILAC process is only intended to be used as a part of the dedication process and in lieu of commercial grade surveys by licensees and suppliers of basic components.

3.2 TECHNICAL EVALUATION

As part of the commercial grade dedication process, the purchaser will perform and document a technical evaluation for the calibration and testing services being procured. This technical evaluation includes identification of the safety function to be performed, the credible failure modes, the critical characteristics, and requirements for the purchase of calibration and/or testing services that need to be included in the purchase documents. The purchaser may perform a single technical evaluation for calibration services and a single technical evaluation for testing services and apply them to future procurements provided the technical evaluation covers the scope of services being procured.

Section 6.1 identifies the critical controls/characteristics for calibration and testing services and provides an evaluation of the ability for the ILAC process to control the critical characteristics. The evaluation concludes that the critical controls/characteristics are included in the ISO/IEC-17025:2017 standard requirements and are verified to be properly controlled by a laboratory as part of the ISO/IEC-17025:2017 accreditation process. When procuring calibration and testing services, the purchaser needs to verify that the laboratory's scope of accreditation covers the scope of services being procured. For calibration services, the published scope of accreditation for the calibration laboratory must cover the needed measurement parameters, ranges, and uncertainties. For testing services, the published scope of accreditation for the test laboratory must cover the needed testing services including test methodology and tolerances/uncertainty.

There are two situations in which commercially procured laboratory services may be used as part of the commercial grade dedication process. The first situation is when the laboratory service is procured as a stand-alone service that is being dedicated. This is typical for calibration services, but may also occur for some testing services. The guidance described herein is for the dedication of the laboratory service itself for which a commercial grade dedication technical evaluation is needed to address the dedication of the laboratory services.

The second situation is when the laboratory service is procured as part of a larger dedication package (e.g., where a commercial test is used as one part of the dedication of a commercial item). For example, the Charpy V-notch test when the material's fracture toughness or impact resistance is a critical characteristic for dedicating the material. Under this scenario, the dedicating entity needs a technical evaluation addressing the safety function and critical characteristics of the commercial grade item itself in addition the technical evaluation for the laboratory services. Therefore, two technical evaluations are required: one for the dedication of the laboratory service and one for the dedication of the commercial grade item.

For both situations discussed above, the purchaser, as part of the evaluation of the laboratory, will verify that the laboratory is accredited to ISO/IEC-17025:2017, "General requirements for the competence of testing and calibration laboratories," by an Accreditation Body that is a signatory to the ILAC Mutual Recognition Arrangement, and the services being procured are included in the scope of the laboratory's accreditation.

3.3 ACCEPTANCE METHOD

Purchasers should document in their dedication plan the use of commercial calibration and test laboratories accredited to ISO/IEC 17025:2017 by ILAC signatories in lieu of performing a commercial grade survey. To assure the critical characteristics are met, the purchaser should document that the acceptance method needs to include verification that the laboratory is accredited to ISO/IEC-17025:2017, "General requirements for the competence of testing and calibration laboratories," by an Accreditation Body that is a signatory to the ILAC Mutual Recognition Arrangement, and that the procured services are within the laboratory's scope of accreditation.

A documented review of calibration and testing records will be completed in order to implement the acceptance method. The purchaser needs to verify, at receipt inspection, that the laboratory has certified that it provided the service in accordance with their accredited ISO/IEC-17025:2017 program and scope of accreditation, and have complied with any other requirements specified in the Purchaser's procurement documents.

3.4 LIMITATIONS OF USE

The guidance provided in this document was developed for use as a part of the commercial grade dedication process for laboratory calibration and testing services by licensees and suppliers of basic components. It is recognized that commercial suppliers that do not implement a 10 CFR 50, Appendix B program routinely utilize sub-tier suppliers of calibration and testing services based these sub-tier suppliers' accreditation to ISO/IEC 17025:2017. During dedication of items or services from commercial suppliers, licensees and 10 CFR 50, Appendix B suppliers are reminded that the

guidance of EPRI 3002002982, "Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications" applies. Therefore, when Method 2, "Commercial Grade Surveys" are utilized as an acceptance method, the survey report must document the commercial supplier's control over the identified critical characteristics and the associated quality controls that affect the critical characteristics such as calibration of Measuring and Test Equipment (M&TE). The survey report must document the acceptability of the commercial supplier's control over calibration and not merely state the commercial supplier uses accredited calibration or testing service providers based on accreditation to ISO/IEC 17025:2017. Survey reports should address the selection and approval of supplier and the overall procurement controls as applicable for such suppliers.

EPRI 3002002982 discusses commercial grade dedication of services. The document recognizes that Nondestructive Examination (NDE) services or Nondestructive Testing (NDT) services can potentially be dedicated. For the purpose of this document, the terms NDE and NDT are considered equivalent and can be used interchangeably. However, the ILAC process is not intended for the dedication of NDE services based on the laboratory's accreditation to ISO/IEC 17025:2017. There are specific personnel qualification and certification requirements for personnel performing NDE activities for the nuclear industry that may not be addressed during the accreditation process. Therefore, to avoid misuse of the accreditation process, NEI 14-05A cannot be used to dedicate NDE services (including ASME Code and non-Code safety related applications) in lieu of a commercial grade survey. It should be noted that use of the ILAC process to dedicate NDE services required by ASME Code is also prohibited by ASME Code.

With regard to the procurement of both calibration and testing services, the procurement document must prohibit the accredited calibration or testing laboratory from subcontracting the service being procured. The disallowance of subcontracting the service being procured will help reduce the chance of misuse of the ILAC process and not receiving an accredited service. The procurement document for accredited services must be submitted directly to the entity performing the calibration or testing.

4 PURCHASER'S QUALITY ASSURANCE PROGRAM

Purchasers that rely on the accreditation by ILAC signatories in lieu of commercial grade surveys are required by 10 CFR Part 50, Appendix B to document this alternative method in their QA program. The following sections discuss criteria that need to be addressed in the QA Program in order to credit the ILAC process. The purchaser will qualify the service provider as described in Section 3 of this guidance, and will impose any additional technical or quality program requirements, as necessary, to meet regulatory

requirements and purchaser QA program commitments. A template for describing the use of the ILAC process in lieu of a commercial grade survey in a purchaser's QA Program is provided in Appendix A. Although a purchaser is not required to use the template in Appendix A, all of the actions and steps described in Appendix A need to be included in the purchaser's QA Program.

In addition, a commercial grade dedication technical evaluation is required since the implementation of the ILAC process is a part of the commercial grade dedication process. The technical evaluation must identify safety function and the critical characteristics of the calibration or testing services along with the acceptance method(s). This document includes a sample technical evaluation/dedication plan for dedicating calibration services and one for dedicating laboratory testing services. Although a purchaser is not required to use the attached example technical evaluations, these technical evaluations represent acceptable technical evaluations for dedicating calibration and testing services.

4.1 ORGANIZATION

The purchaser retains overall responsibility for assuring that purchased calibration and/or testing services meet applicable technical and regulatory requirements and that reasonable assurance of quality is provided.

4.2 PROCUREMENT DOCUMENT CONTROL

When purchasing commercial grade calibration or testing services from laboratories accredited by an ILAC signatory, the procurement documents will impose additional technical and quality requirements, as necessary, to satisfy the purchaser's QA Program and technical requirements. These include as a minimum:

- 1) The service must be provided in accordance with their accredited ISO/IEC-17025:2017 program and scope of accreditation.
- 2) As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out of tolerance. *(for calibration services only)*
- 3) The equipment/standards used to perform the calibration must be identified in the certificate of calibration. *(for calibration services only)*
- 4) Subcontracting of these accredited services is prohibited.
- 5) The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
- 6) Performance of the services listed on this order is contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the Accreditation Body within the past 48 months.

- 7) Any additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

4.3 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

In lieu of a commercial grade survey, purchasers can take credit for accredited ISO/IEC-17025:2017 programs for commercial grade calibration and testing services suppliers by ILAC Accreditation Bodies provided purchasers validate at receipt inspection, the service provider's documentation meets and supports their scopes of accreditation for the contracted calibration / test service, as-found calibration data is provided when calibrated items are found to be out-of-tolerance, and that purchase order technical and quality requirements are met.

For commercial grade calibration and testing service providers with programs accredited by ILAC signatories, the reliance on this accreditation process and adherence to ISO/IEC-17025:2017 requirements provide for the integrity of the technical data produced as well as the necessary evidence of compliance for the qualification of calibration or test suppliers under a commercial grade dedication process. Purchasers using the accredited laboratories will be responsible for reviewing objective evidence for conformance to the procurement documents, such as review of documentation to validate the service providers' accreditation and review of the actual certificates provided by the laboratory. The purchasers do not need to directly perform technical verification of data produced nor do they need to perform commercial grade surveys of the accredited laboratory activities.

Purchasers will review the objective evidence for conformance to the procurement documents as part of the dedication process to verify that the technical and quality requirements identified in the purchase documents are met.

4.4 CONTROL OF MEASURING AND TEST EQUIPMENT

ISO/IEC-17025:2017 does not require that the accredited supplier provide as-found calibration data when the item being calibrated is found to be out-of-tolerance. Since this data is needed to support the purchaser in performing the required evaluations for potentially impacted services, an additional requirement will be imposed via the procurement documents for the accredited laboratory to provide as-found calibration data when the item being calibrated is found to be out-of-tolerance. This will also support the evaluations necessary to meet the purchaser's obligations for reporting any defects and non-compliance as required by 10 CFR Part 21.

4.5 CORRECTIVE ACTION

ISO/IEC-17025:2017 does not require the laboratory to notify the AB of any significant condition adverse to quality, and ISO/IEC-17011:2017 does not require the AB to notify the Region or ILAC of any significant conditions adverse to quality. Although ILAC procedures require laboratories to notify the AB of a condition that potentially impacts their scope of accreditation within a given period of time (typically 30 days), the notification is not required to be immediate.

Since this data is needed to support the purchaser in performing the required evaluations for potentially impacted services, an additional requirement will be imposed via the procurement documents for the accredited laboratory to provide notification of any significant conditions adverse to quality. Based upon the conclusion that the laboratory scope of accreditation encompasses the critical characteristics and because the ILAC process does not use the term “significant condition adverse to quality,” an equivalent requirement would be for the laboratory to notify the purchaser of any condition that adversely impacts the laboratory’s ability to maintain the scope of accreditation.

5 U.S. NUCLEAR INDUSTRY OVERSIGHT OF THE ILAC PROCESS

The objective of the continued oversight of the ILAC process by the U.S. nuclear industry is to confirm that the ILAC process can continue to be used in lieu of commercial grade surveys as part of the purchaser’s commercial grade dedication activities. This oversight will monitor ILAC activities to verify that requirements and procedures used in the ILAC process (e.g., ISO/IEC-17011:2017 and ISO/IEC-17025:2017) continue to be consistent with the NRC accepted practices, and that the ILAC process continues to be implemented in conformance with ILAC standards and procedures. Early identification of potentially adverse changes will also afford the nuclear industry the opportunity to discuss any impact with the NRC and to modify this guidance as necessary.

5.1 ORGANIZATION

NEI has formed an industry team, consisting of licensees (including NUPIC members) and suppliers, to monitor ILAC activities as they relate to industry’s use of the ILAC process as part of commercial grade dedication. NEI is a stakeholder member of ILAC as a liaison for the nuclear industry and provides to its licensee and supplier members access to ILAC information and activities in an effective and efficient manner. Membership in ILAC permits attendance at meetings, receipt of notification of potential changes to ILAC requirements and guidelines (including related international standards), and is

important for access to observing peer evaluations and laboratory assessments. The NEI team has a close association and coordinates with the NUPIC membership for monitoring of the ILAC process.

NUPIC has formed a group to support the industry's efforts to monitor the ILAC process. NUPIC plays a central role in the continued oversight activities, and a NUPIC member leads or participates in many of the oversight activities described below.

5.2 VERIFICATION THAT THE ILAC PROCESS CONTINUES TO BE CONSISTENT WITH NRC ACCEPTED PRACTICES

The assessments and conclusions of the rigor of the ILAC process documented herein are based in large part on the evaluation of the ILAC requirements and procedures. The comparison of ILAC requirements and procedures, in particular standard ISO/IEC-17025:2017, to NRC requirements, NRC endorsed guidance, and NUPIC checklists, which conform to these requirements and guidance, is the primary basis for the approach documented within to use the ILAC process in lieu of a commercial grade survey.

As part of the continued oversight, the nuclear industry (NEI, NUPIC members, and other industry representatives) will monitor the ILAC requirements and procedures to verify that they continue to be consistent with NRC accepted practices. Because ISO/IEC-17025:2017 is the main standard that assures consistency with NRC accepted practices and because it is not often revised, it is expected that changes that would make the ILAC process no longer be consistent with NRC accepted practices would be few and infrequent, if at all. A summary of the monitoring of ILAC requirements and procedures will be documented on an annual basis.

As a Stakeholder Member, NEI has the ability to participate in the process to maintain ILAC requirements and procedures. If changes are proposed, NEI will be notified by ILAC of the potential change. The NEI team, including members from NUPIC, will evaluate whether the potential changes could materially affect the manner in which the ILAC process is used by the nuclear industry. If changes would result in the ILAC process no longer being consistent with NRC accepted practices, then the nuclear industry has the ability to provide feedback in writing and at ILAC Arrangement Committee meetings that oversee ILAC policies. The nuclear industry would also make the NRC aware of any potential adverse changes and industry's actions to mitigate them.

If changes to ILAC requirements and procedures are implemented that result in the ILAC process no longer being consistent with NRC accepted practices, then the nuclear industry and NRC would have substantial advanced notification, and would have time to implement changes to this guidance or otherwise issue communications to users of the guidance.

5.3 VERIFICATION THAT IMPLEMENTATION OF THE ILAC PROCESS CONTINUES TO BE CONSISTENT WITH NRC ACCEPTED PRACTICES

The assessments and conclusions of the rigor of the implementation of the ILAC process documented herein are based in part on the direct observations of the performance of peer evaluations of ABs. These peer evaluations are performed to verify the ABs adherence to ISO/IEC-17011:2017, and their ability to accredit laboratories to ISO/IEC-17025:2017. The U.S. nuclear industry's observation of these peer evaluations and associated laboratory assessments provide additional confidence in the ILAC processes.

As part of the continued oversight, the nuclear industry (NEI, NUPIC, and other industry representatives) will observe Peer Evaluations of an AB and the associated assessments of calibration and testing laboratories to verify that the ILAC process continues to be implemented consistent with ILAC requirements and procedures. U.S. nuclear industry observations of peer evaluations will be performed on a frequency of once every three years. This frequency is consistent with the guidance in EPRI NP-5652 to establish the frequency for commercial grade surveys. These observations will be led by a knowledgeable NUPIC member with support from other NEI team members. The NRC may request to participate on these observations.

5.4 OPTIONAL ACTIVITIES

Several additional monitoring activities are available to the nuclear industry as ILAC stakeholder members, but are not necessary to achieve the objectives of the industry's continued oversight. These activities may provide additional benefits to the efficiency of the industry's monitoring efforts and will be considered as optional activities.

Through NEI's stakeholder membership in ILAC, the nuclear industry is permitted to attend general ILAC meetings. These meetings may provide additional information on the ILAC process and interaction with other ILAC members, but are otherwise not essential to the industry's continued oversight. Similarly, the ability to attend peer evaluator training offered by one of the Regions may provide additional insight into the ILAC process, but is not essential to the industry's continued oversight.

6 NUCLEAR INDUSTRY REVIEW OF THE ILAC PROCESS

The ILAC process was assessed by the nuclear industry to determine its rigor and whether it could satisfy requirements for commercial grade dedication of calibration and laboratory services. This assessment was based upon an evaluation of the ILAC procedures, training, MRA meetings, and observations of peer evaluations and laboratory assessments. The ILAC process was compared to NRC requirements, NRC endorsed

guidance and NUPIC practices, which conform these requirements and guidance for performing commercial grade surveys to determine if the ILAC process is equivalent.

It was concluded that the ILAC process is equivalent to NUPIC practices when the following four items are addressed by the inclusion of requirements in the procurement documents:

1. ISO/IEC-17025:2017 does not require the laboratory to include as-found calibration data in the Certificate of Calibration when calibrated items are found to be out of tolerance.
2. ISO/IEC-17025:2017 does not require the laboratory to identify in the certificate of calibration, the standards used to perform the calibration.
3. ISO/IEC-17025:2017 does not require the laboratory to notify the AB of any significant condition adverse to quality, and ISO/IEC-17011:2017 does not require the AB to notify the Region or ILAC of any significant conditions adverse to quality. Based upon the conclusion that the laboratory scope of accreditation encompasses the critical characteristics and because the ILAC process does not use the term “significant condition adverse to quality,” an equivalent requirement would be for the laboratory to notify the purchaser of any condition that adversely impacts the laboratory’s ability to maintain the scope of accreditation.
4. The NRC's original endorsement of the use of accreditation to ISO/IEC 17025 by Accreditation Bodies (ABs) that are signatories to the ILAC MRA in lieu of performing a commercial grade survey for the acceptance of calibration and testing services was largely based on ABs performing on-site accreditation assessments at laboratories. Due to travel restrictions caused by the COVID-19 pandemic, ABs are performing remote accreditation assessments. While use of remote accreditation assessments were determined by the industry to be acceptable during extenuating circumstances, the industry found it necessary to impose a limitation on the use of remote assessment for laboratories performing calibrations and testing for licensees and suppliers of basic components. Such laboratories cannot maintain accreditation based on consecutive remote accreditation assessments. This will maintain the spirit and intent of ISO/IEC 17011 which requires onsite assessments every 24 months. ISO/IEC 17011 does allow the use of remote assessments if the AB determines a remote assessment can be justified. Currently, NUPIC Commercial Grade surveys are required to be performed on-site at the supplier's facility. Extenuating circumstances include: 1) declaration of a national emergency; 2) severe localized or national weather conditions or damage to licensee or supplier infrastructure; or 3) localized outbreak of a severe health concern to the public and licensee.

Two additional differences with NUPIC practices were identified, but determined to be acceptable and thus do not need to be addressed through the inclusion of requirements in the procurement documents.

1. ISO/IEC-17025:2017 Section 7.1 requires the laboratory to establish and maintain the capability and resources to meet purchaser's procurement requirements. However, it was noted during an observation of a peer evaluation, that the AB assessment of the laboratory only verified that the laboratory could meet procurement document requirements related to the scope of accreditation, and did not evaluate the capability to meet requirements not related to the scope of accreditation. This is acceptable because the scope of accreditation encompasses the critical characteristics, and thus there is reasonable assurance that the requirements of 10 CFR Part 21 and 10 CFR Part 50, Appendix B will be met for the dedicated service. Furthermore, this difference cannot be addressed through a requirement in the procurement documents, because the purchaser does not have the capability to independently verify it. However, this difference was discussed with ILAC representatives, who indicated that they would consider if training could be enhanced to clarify that assessments should include verification of the ability to comply with all special contract requirements, and are not limited to only those specifically related to the scope of accreditation.
2. ISO/IEC-17025:2017 includes quality controls that address suspect counterfeit and fraudulent items. In particular, Sections 6.6 and 7.1 establish requirements for subcontracting tests and calibrations, including verification that the subcontractor is accredited and notification to the purchaser when subcontracting these services. Section 4.6 establishes requirements for purchasing services and supplies, including inspections to verify that they meet the requirements and the evaluation of suppliers. However, ISO/IEC-17025:2017 does not include a specific requirement for laboratory controls to identify suspect counterfeit and fraudulent items. NUPIC checklists include a question that would identify controls the supplier has in place to prevent ingress of suspect counterfeit or fraudulent items. The risk of counterfeit and fraudulent items is low in an environment that procures and uses traceable standards to perform calibration. However, counterfeit or fraudulent items could enter the supply chain in certain cases, such as when the laboratory subcontracts calibration services and the subcontractor misrepresents their accreditation. The topic of counterfeit and fraudulent items was discussed with ILAC representatives, who indicated that the topic would be discussed further by ILAC membership to determine if any enhancements to the ILAC process are warranted. EPRI updated guidance on counterfeit and fraudulent items, "Plant Support Engineering: Counterfeit, Fraudulent and Substandard Items," EPRI-1019163 Revision 1 in 2014. Use of the EPRI

guidance on counterfeit and fraudulent items is voluntary; however, it does provide practical measures to further enhance protections against counterfeit and fraudulent items and includes a standard procurement clause that could be used in the procurement of calibration and testing services.

It should be noted that the original industry review of the ILAC process was performed to ISO/IEC 17025:2005 and ISO/IEC 17011:2004. However, the conclusions drawn from the review remain unchanged and apply to ISO/IEC 17025:2017 and ISO/IEC 17011:2017 since the later versions of these standards were found to be equivalent to the earlier versions.

6.1 TECHNICAL EVALUATION OF ILAC REQUIREMENTS AND PROCEDURES

A technical evaluation of the ILAC requirements and procedures was performed in order to assess whether the ILAC process is an acceptable alternative to commercial grade surveys for dedication. ISO/IEC-17025: 2017, “General requirements for the competence of testing and calibration laboratories,” and ISO-17011: 2017, “Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies,” were reviewed and compared with NUPIC checklists for supplier surveys. Based upon this evaluation, it is concluded that 1) the ILAC process meets the criteria for a commercial grade survey, and 2) the ISO/IEC-17025: 2017 standard is equivalent to the critical characteristics identified in the NUPIC Commercial Grade Item Survey Checklist and Commercial Grade Calibration Services Checklist.

Acceptable Alternative Method

For a commercial grade survey, EPRI guidance and NRC Commercial Grade Dedication Inspection Procedure 43004 indicate that the commercial grade surveys should be used when:

1. The purchaser desires to verify one or more of the critical characteristics based on the merits of a laboratory's commercial quality controls.
2. The laboratory has a documented and effectively implemented program and/or procedures to control the critical characteristics of the services being procured.
3. The survey should be conducted by an individual(s) that is also trained in auditing and knowledgeable in the operation of the item(s) and the associated critical characteristics to be verified.
4. The verification is accomplished by reviewing the vendor's program/procedures controlling these characteristics and observing the actual implementation of these

controls in the manufacture of items identical or similar to the items being purchased.

All of the above criteria are met for laboratories accredited to ISO/IEC-17025:2017 by AB's that are signatories to the ILAC MRA. Therefore, the ILAC process is an acceptable alternative to performing commercial grade surveys.

Critical Characteristics

The technical evaluation includes identification of critical characteristics as part of the dedication process. Below are lists of the typical critical characteristics for calibration services and laboratory testing services.

Critical Characteristics for Calibration Services

The critical controls/characteristics for calibration services are identified in the NUPIC Commercial Grade Calibration Survey Checklist and consist of the following attributes. These characteristics apply to all calibration services regardless of the type of Measuring & Test Equipment (M&TE):

- Traceability of calibration and calibration standards to nationally recognized standards (e.g., NIST), equivalent international standards or other acceptable measurement standards (intrinsic)
- Calibrations performed in accordance with written procedures/instructions
- Documented training/qualification of personnel
- Environmental conditions, e.g., temperature, humidity, vibration, etc.
- Adequacy, accuracy, stability, tolerances (uncertainty) and range of measurement standards
- Intervals of calibration for standards
- Software control, e.g., adequate review/approval, verification, validation, error notification, etc.
- Calibration status
- Out of tolerance & corrective action
- Subcontractor calibration controls
- Calibration certification documentation

Entities performing commercial grade dedication of calibration services must document a commercial grade dedication technical evaluation which includes the safety function, critical characteristics and acceptance method(s) for the service. The failure modes and effect analysis are not necessarily required since the critical characteristics are known. Attachment 1 of this document includes an acceptable technical evaluation for the dedication of commercial calibration services.

Critical Characteristics for Laboratory Testing Services:

While NUPIC does not have a standard survey checklist for laboratory testing services, licensees have widely determined the following critical characteristics to apply to all testing services regardless of the type of testing being performed:

- Identification/traceability of the item during testing and processing is maintained.
- Testing for the required characteristics/parameters is performed in accordance with written industry recognized standards or other validated and approved test methods.
- Actual testing is performed in accordance with written and approved procedures.
- Testing is performed by trained and qualified personnel.
- M&TE including chemical standards are calibrated as applicable and are traceable to national or international standards, or intrinsic properties/natural law.
- Traceability of the test results to the item being tested is maintained.
- Certification includes test results, identification of the item, test method used, results, and signature of responsible laboratory authority.

Entities performing commercial grade dedication of laboratory testing services must document a commercial grade dedication technical evaluation which includes the safety function, critical characteristics and acceptance method(s) for the service. The failure modes and effect analysis are not necessarily required since the critical characteristics are known. Please note that Attachment 2 of this document includes an acceptable technical evaluation for the dedication of commercial laboratory testing services.

Review of the ISO/IEC-17025:2017 standard and observations of the accreditation process by NEI/NUPIC has determined that each of the above critical characteristics are

included in the ISO/IEC-17025:2017 standard and are verified to be properly controlled by a laboratory as a part of the ISO/IEC-17025:2017 accreditation process.

Supplier's Quality Program

In order for laboratories to be accredited to ISO/IEC-17025:2017, they must have an adequately documented quality program. The laboratory also needs to comply with any additional quality requirements specified in the procurement documents. The quality program of an accredited supplier is adequate for the purchaser's commercial grade dedication activities, which must be invoked in a procurement document.

6.2 OBSERVATION OF TRAINING

An observation of the ILAC/APLAC Evaluator Training Course was performed in order to gain a comprehensive understanding of the capabilities and experience of assessment personnel, and to evaluate the rigor of the training. Based upon these observations, it was concluded that ILAC/Regional training for peer evaluators is essentially equivalent to NUPIC auditor training.

The training course consists of ten modules presented over a three-day period and it was conducted by senior representatives of Accreditation Bodies. The class that was observed consisted of 17 individuals from 12 different countries. Students are recommended by AB leadership and must pass a screening process (at the regional level), which may include demonstrating written and oral capability in the English language.

The training session included the establishment of scenarios for each of the teams with questions and deliverables assigned for each activity. Specific activities assessed through this process included team selection, agenda development, and activity scheduling. Each team was provided a unique scenario that was challenging and realistic. Each training instructor, as well as several students, shared their experience in performing these evaluations. It became apparent to the students that the resources allocated to the assessment are a key decision and deployment strategies are not identical. Each group performed well and used several different acceptable strategies. For example, one group used a "vertical slice" approach, having each individual look at each element in their area; while other groups used an approach which parceled out individual sections.

A detailed walk through of the Standard Checklist was performed. Each question was discussed and expectations as to what was required were provided for each question. The training instructors shared personal experience in each area addressed. Active participation was noted with very good questions being asked at appropriate times.

It was reinforced that recognition decisions are made by competent persons based on the results of the peer evaluations; therefore, it was emphasized that enough accurate information must be provided to allow for appropriate decisions.

Training includes a section that mirrors many of the requirements of 10 CFR Part 50, Appendix B. The presentation to the training class was very effective and represented the material in the handouts.

Training emphasized the importance of maintaining independence. Each team was provided with a unique scenario with different challenges and issues. Teams worked for one hour to evaluate the organizational structures and legal entities. The teams were provided immediate feedback on their presentations. Similar to previous courses, the learning was achieved through the student engagement with appropriate references with training instructors providing key insights which contributed to the learning experience. Organizational learning was accomplished through review of the individual scenarios with the entire class. The effectiveness of this training, as evidenced by interviews with students and facilitators, was determined to be very good.

Additional training sessions focused on the writing of findings and other issues. The class was tasked with documenting appropriate findings from a set of information provided. The instructors placed a significant amount of focus on improving the strength and consistency in the student's ability to write findings and document issues. This included developing appropriate problem statements based upon objective evidence. It was judged that the capabilities of the students exiting the class to write findings were on par with the capabilities of auditors at the completion of NUPIC training.

This training is favorably compared to NUPIC Lead Auditor training in as much as most Lead Auditor classes have an element of role playing with various scenarios played out and discussions are held critiquing the team. In addition, the observed training contained elements of NUPIC's annual auditor training which is held each February where the auditors are brought up to date on changing regulations and changes to the checklist.

6.3 OBSERVATION OF A MUTUAL RECOGNITION ARRANGEMENT MEETING

An observation of an APLAC MRA meeting was performed in order to evaluate the rigor of the recognition decision making process. The purpose of the MRA council is to review and ensure standards for accreditation are established and met. The MRA meeting was observed to be a rigorous process and was well controlled and implemented. Based upon these observations, it was concluded that the ILAC/Regional decision-making process is essentially equivalent to NUPIC practices.

The APLAC MRA meeting lasted three days, during which decisions on initial accreditations and renewals were made. It was observed that the group was very effective and demonstrated excellent technical skills and management capabilities. The technical capabilities were evident; however, as with most technical groups, the challenge is in regard to auditing and “understanding” the standard and not “rationalizing” the standard. The MRA has achieved a good balance and works effectively through these challenges.

It was noted that many challenges that the MRA is addressing have been addressed by NUPIC; examples include team formation and the use of technical specialists during evaluation (audit) and surveillances, team feedback, scorecards, and sharing of operating experience. Differences between regions poses a challenge, while at the same time creating a dynamic that encourages continuous improvement.

During the meeting, a decision on the initial assessment of a national accreditation body was made. The MRA council considered the report from the peer evaluation team for the initial assessment, which it reviewed prior to the meeting and was also presented by the team leader at the meeting. The team recommended approval of the accreditation body on the basis of their review of the responses to the issues identified in the peer evaluation. The evaluation included several locations, key meetings and other activities, and was conducted after the accreditation body addressed all of the findings from the earlier performed pre-peer evaluation. The questioning and process of the MRA council deliberation was rigorous. Finally, the accreditation body was requested to leave, and the MRA council voted to make their decision. The accreditation body was approved and accepted as an APLAC/ILAC MRA signatory.

The MRA council also reviewed an accreditation body for a four-year re-evaluation that was requesting to expand their approved scope of services. In this case, the peer evaluation concluded that the accreditation body met all ILAC requirements, but also identified two non-conformities and three deficiencies. The accreditation body addressed all non-conformities and deficiencies to the satisfaction of the peer evaluation team, and the team recommended approval. The questioning and process of the MRA council deliberation followed the rigor previously described. It was noted that the IAAC process is different from APLAC as they send reports out prior to the meeting and questions are sent to the team lead as a lead up to the meeting. In addition, all issues are reviewed and discussed during the decision-making meeting. This does not appear to be a significant difference.

Several other peer evaluations were reviewed by the MRA council with the same level of rigor as previously described.

The MRA council also reviewed the list of candidates for lead peer evaluator and approved four new team leaders. The Evaluator Performance Working Group reviews

candidates and makes recommendations to the full MRA. This is not an automatic process and there are many controls in place to assure the high quality of evaluators.

6.4 OBSERVATION OF PEER EVALUATIONS AND LABORATORY ASSESSMENTS

Observations of peer evaluation of ABs and assessments of laboratories were performed in order to verify that the ILAC process is implemented according to relevant requirements and procedures and to verify the implementation is an acceptable alternative to a commercial grade survey for dedication. Based upon these observations, it is concluded that the implementation of the ILAC process is essentially equivalent to NUPIC practices for supplier surveys.

Observation of Peer Evaluation of the Japan Accreditation Body

A NUPIC/NEI team, led by a NUPIC member, observed the Asia Pacific Laboratory Accreditation Cooperation (APLAC) peer evaluation of the Japan Accreditation Board (JAB) the week of November 11, 2013. The team observed the APLAC entrance meeting, the evaluation of JAB, the evaluation of JAB assessment of calibration and testing laboratories, and the exit meeting.

Observation of Peer Evaluation of the American Association for Laboratory Accreditation

A NUPIC/NEI team, led by a NUPIC member, observed the joint APLAC/IAAC peer evaluation of the American Association for Laboratory Accreditation (A2LA) the week of March 3, 2014. The team observed the APLAC/IAAC entrance meeting, the evaluation of A2LA, the evaluation of A2LA assessment of a testing laboratory, and the exit meeting.

Conclusions

The activities observed were found to be essentially equivalent to NUPIC practices for acceptance Method 2 – Commercial Grade Survey – for dedication of commercial grade calibration and laboratory services. The following are details from the observation that support this conclusion:

- The observation team verified that the overall operations of the peer evaluation under the ILAC process is robust, comprehensive, and in compliance with ISO/IEC-17011:2004.
- The peer evaluators under the ILAC process were found to be true peers in that they currently lead or direct other Accreditation Bodies.

- The peer evaluation process was found to be performance-based and included real time observations of testing and calibration services. All evaluations observed were of high standard.
- Lead assessor and technical assessors/experts were found to be very knowledgeable and possessed extensive experience in the areas assessed and they were very familiar with the assessment process. The competence of the assessors and evaluators is a key strength of the ILAC process.
- The overall operation of ABs is in accordance with the requirements of ISO/IEC-17011:2004.
- Scope of accreditation specified by ABs and the laboratories was verified to accurately reflect the capabilities of the laboratory.
- AB staff members are skilled and technically qualified for the functions they perform. They have well established accreditation processes which are applied consistently to the accreditation of their testing and calibration laboratories.
- Laboratories accredited by ABs have been assessed against and found to comply with the requirements of ISO/IEC 17025:2005/2017.
- The accreditation assessments were found to be technically equivalent to or better than a NUPIC style commercial grade survey. Both the management system and technical operation of the laboratories were effectively assessed.
- The Accreditation Assessment process was found to be performance-based and included real time observations of testing and calibration services. All assessments observed were of a high standard.

It should be noted that the original industry observations of the ILAC peer evaluations were performed to ISO/IEC 17025:2005 and ISO/IEC 17011:2004. However, the conclusions drawn from these observations also apply to ISO/IEC 17025:2017 and ISO/IEC 17011:2017 since the later versions of these standards were found to be equivalent to the earlier versions.

APPENDIX A – QUALITY ASSURANCE PROGRAM TEMPLATE

A.1.a Dedication of Commercial Grade Items

Commercial grade items (items not originally designed or manufactured as a basic component) are subject to a commercial grade dedication process as defined and authorized by Engineering in accordance with procedures that meet the requirements of the NRC, before such items are approved for safety-related applications. Commercial grade dedication also applies to a commercial grade service that is associated with basic component hardware, design certification, design approval, or information in support of an early site permit application under 10 CFR Part 52, whether these services are performed by the component supplier or others (e.g., safety-related design, analysis, inspection, testing, or fabrication that is associated with a basic component).

Procedures are established to describe the responsibilities for Engineering to perform a technical evaluation, select applicable critical characteristics, and determine an appropriate dedication method for acceptance. Procedures are also established to enhance the detection of counterfeit and fraudulent items and to minimize the likelihood of the introduction of such items in safety-related applications.

[Purchaser] may utilize commercial grade items or services in its supply of basic components in a manner consistent with the guidance in [Generic Letter (GL) 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products.” GL 89-02 documents the NRC’s conditional endorsement of EPRI NP-5652, “Guideline for the Utilization of Commercial grade Items in Nuclear Safety Related Applications” (NCIG-07).] In addition, Regulatory Guide 1.164 documents the NRC's endorsement of EPRI TR 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications," Revision 1 to EPRI NP-5652 and TR-102260.

[Purchaser] utilizes a commercial grade dedication process consistent with Generic Letter 89-02 and 10 CFR 21 for the supply of basic components. When a commercial grade item is modified, inspected, and/or tested to demonstrate compliance to requirements more restrictive than the manufacturer’s original specifications such item is uniquely identified as different from the commercial grade (off-the-shelf) item and traceable to documents that record the difference.

When purchasing commercial grade calibration or testing services from a laboratory holding accreditation by an accrediting body recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), commercial grade surveys need not be performed provided each of the following conditions are met:

1. A documented review of the supplier's accreditation is performed and includes a verification of the following:
 - a. The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories."
 - b. For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
 - c. For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty.
 - d. The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.
2. The purchase documents require that:
 - a. The service must be provided in accordance with their accredited ISO/IEC-17025:2017 program and scope of accreditation.
 - b. As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance. (*for calibration services only*)
 - c. The equipment/standards used to perform the calibration must be identified in the certificate of calibration. (*for calibration services only*)
 - d. Subcontracting of these accredited services is prohibited.
 - e. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
 - f. Performance of the services listed on this order is contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the Accreditation Body within the past 48 months.
 - g. Additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.
3. It is validated, at receipt inspection, that the laboratory's documentation certifies that:
 - a. The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2017 program, and has been performed within their scope of accreditation, and
 - b. The purchase order's requirements are met.

As discussed in Section 3.4 of this document, NEI 14-05A cannot be used to dedicate NDE services (including ASME Code and non-Code safety related applications) in lieu of a commercial grade survey.

A commercial grade dedication technical evaluation is required to document the critical characteristics and acceptance methods when dedicating calibration services based on the ILAC Process. The same is true for the dedication testing services. Attachment 1 and Attachment 2 of this document include acceptable examples of a technical evaluation for calibration services and testing services, respectively.

SECTION A ITEM/SERVICE DESCRIPTION – CALIBRATION SERVICES

This Technical Evaluation addresses M&TE calibration services from commercial calibration service providers including ISO/IEC 17025:2005/2017 accredited laboratories and non-accredited service providers. It provides the Commercial Grade Item (CGI) dedication requirements for commercial calibration services. The critical characteristics are same whether one verifies the critical characteristics via a commercial grade survey or takes credit for the laboratory being accredited to ISO/IEC 17025:2005/2017 as detailed in NEI 14-05A. NEI 14-05A has been endorsed by the US NRC and allows the dedicating entity to take credit for verification of the critical characteristics by virtue of the laboratory being accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body (AB) which is signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) in lieu of performing a commercial grade survey to verify the laboratory's control over the critical characteristics. This evaluation also covers the calibration of new M&TE, recalibration of M&TE on assigned intervals, calibration of M&TE that has been repaired, reworked or updated, and on-site calibration services by calibration supplier's service representatives.

SECTION B END USE / PARENT / HOST EQUIPMENT INFORMATION

Note: If the specific end-use(s) / plant applications are not known, complete Section C of this form in lieu of Section B prior to proceeding.

Not Applicable (Section C Completed Below)

EQUIPMENT ID (TAG) NUMBERS OR DESCRIPTION OF ITEM/SERVICE USAGE:**PARENT COMPONENT / HOST DESCRIPTION:****FUNCTIONAL SAFETY CLASS OF COMPONENT / HOST:**

- Safety-Related
 Non-Safety Related (If non-safety, item/service is not a candidate for dedication)

BASIS / SOURCE:**IDENTIFICATION OF PARENT COMPONENT / HOST EQUIPMENT FUNCTION(S)**

FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
<input type="checkbox"/> Active		
<input type="checkbox"/> Passive		

PARENT COMPONENT / HOST EQUIPMENT IS (CHECK ALL THAT APPLY):

- | | |
|---------------------------------------------|--------------------------------------------------------|
| <input type="checkbox"/> EQ | <input type="checkbox"/> ASME SECTION III |
| <input type="checkbox"/> CLASS 1E | <input type="checkbox"/> CONTAINMENT PRESSURE BOUNDARY |
| <input type="checkbox"/> SEISMIC CLASS 1 | <input type="checkbox"/> SERVICE LEVEL 1 COATING |
| <input type="checkbox"/> OTHER: (see below) | |

SECTION C BOUNDED SCOPE OF USE

Only complete Section C when specific end-use of the item/service being dedicated is unknown.

Not Applicable (Section B Completed Above)

Is the item/service being dedicated a commodity or standard item/service designed and constructed in accordance with an industry standard?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
--------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------

IF "YES" LIST THE STANDARD(S) BELOW

ISO/IEC 17025:2005/2017, "General Requirements for the Competence of Testing and Calibration Laboratories."

LIST FUNCTIONS AND / OR APPLICATIONS CONSIDERED WHEN COMPLETING THIS EVALUATION

Calibration results and data provided may be used in accordance with the [Enter Company Name] 10 CFR 50 Appendix B QA program to evaluate the ability of safety-related equipment to perform its safety-related design functions.

The basic safety function of calibration services is to verify Measuring & Test Equipment (M&TE) is working properly and providing accurate and reliable data and to make adjustments to M&TE as need to ensure the M&TE is working properly and providing accurate and reliable data.

This TE addresses commercial calibration services for M&TE / standards including those provided by commercial calibration service providers accredited to ISO/IEC 17025:2005/2017 and non-accredited service providers.

EQUIPMENT QUALIFICATION CONSIDERATIONS / LIMITATIONS (CHECK ALL THAT APPLY):**CONSIDERATION**

QUALIFICATION BASIS / LIMITATIONS OF USE: Not applicable. M&TE addressed in this evaluation are not permanently installed in the plant. The actual M&TE is considered non-safety but the calibration of the M&TE is considered safety related.

ENVIRONMENTAL

QUALIFICATION

SEISMIC QUALIFICATION

OTHER: (see below)

SECTION D SERVICE INFORMATION**ITEM/SERVICE DESCRIPTION:**

This technical evaluation covers the commercial grade dedication for the commercial calibration of essentially all Measuring & Test Equipment (M&TE) and standards including electrical, mechanical, dimensional, thermodynamic, etc. A separate technical evaluation is therefore not needed for each calibration service for each instrument since the critical characteristics of the calibration service are identical.

FUNCTIONAL SAFETY CLASS OF ITEM/SERVICE:

- Safety-Related
 Non-Safety Related (If non-safety, item/service is not a candidate for dedication)

BASIS / SOURCE:

The basic safety function of calibration services is to verify Measuring & Test Equipment (M&TE) is working properly and providing accurate and reliable data and to make adjustments to M&TE as need to ensure the M&TE is working properly and providing accurate and reliable data.

IDENTIFICATION OF ITEM/SERVICE FUNCTION(S)

FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
<input checked="" type="checkbox"/> Active <input checked="" type="checkbox"/> Passive	The basic safety function of calibration services is to verify Measuring & Test Equipment (M&TE) is working properly and providing accurate and reliable data and to make adjustments to M&TE as needed to ensure the M&TE is working properly and providing accurate and reliable data.	Calibration services performed by commercial suppliers on behalf of [Enter Company Name] must be controlled in accordance with the [Enter Company Name] 10 CFR 50, Appendix B-compliant QA program. The associated M&TE can then be used by [Enter Company Name] to perform inspections and test in accordance with [Enter Company Name] 10 CFR 50 Appendix B QA program to evaluate the ability of safety-related items to perform their safety-related design functions.

ITEM/SERVICE IS (CHECK ALL THAT APPLY):

- | | |
|-----------------------------------------------------|-------------------------------------------------------------------|
| <input checked="" type="checkbox"/> EQ | <input checked="" type="checkbox"/> ASME SECTION III |
| <input checked="" type="checkbox"/> CLASS 1E | <input checked="" type="checkbox"/> CONTAINMENT PRESSURE BOUNDARY |
| <input checked="" type="checkbox"/> SEISMIC CLASS 1 | <input checked="" type="checkbox"/> SERVICE LEVEL 1 COATING |
| <input type="checkbox"/> OTHER: (see below) | |

SECTION E ELIGIBILITY FOR DEDICATION

Is the item/service eligible for dedication in accordance with 10 CFR Part 21?

Yes No

If the answer is no, this item/service cannot be dedicated.

SECTION F FAILURE MODES / MECHANISMS AND EFFECTS ANALYSIS

CREDIBLE FAILURE MODE/MECHANISM	EFFECTS ON SYSTEM/COMPONENT FUNCTION
Failure Modes/Mechanisms and Effects Analysis is normally performed to help determine the critical characteristics. In the case of calibration services, the critical characteristics are known as specified in NEI 14-05A. Therefore, a FMEA is not required.	Failure Modes/Mechanisms and Effects Analysis is normally performed to help determine the critical characteristics. In the case of calibration services, the critical characteristics are known as specified in NEI 14-05A. Therefore, a FMEA is not required.
BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)	
Failure Modes/Mechanisms and Effects Analysis is normally performed to help determine the critical characteristics. In the case of calibration services, the critical characteristics are known as specified in NEI 14-05A. Therefore, a FMEA is not required.	

SECTION G OPERATING EXPERIENCE / HISTORICAL PERFORMANCE INFORMATION**SOURCES REVIEWED AND RESULTS**

External – An INPO OE search was conducted using the terms “calibration lab,” “vendor calibration,” “calibration dedication,” “calibration cgi,” and “calibration service.”
 The only OE found that is considered pertinent to this evaluation was Information Notice 90-36.

SOURCES REVIEWED AND RESULTS

IN 90-36 documents an apparent falsification of State of Connecticut weight certificates by a calibration service facility. Dedicating entities should be aware that the calibration of measuring devices can only be considered accurate if when the standards used to perform the calibration are in current calibration.

Internal – Include any Internal Operating Experience

Example Only

SECTION H IDENTIFICATION ATTRIBUTES

IDENTIFICATION ATTRIBUTES	DESCRIPTION OF INSPECTION	ACCEPTANCE CRITERIA
Calibration service provider	Visual	Calibration service provider is as specified in the purchasing document for the calibration service performed.
Device Identification	Visual	The device to be calibrated has the same manufacturer and other identification (part/model number, serial number, etc.) specified in the purchasing document for the calibration service.

SECTION I CRITICAL CHARACTERISTICS

ID	CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
1	Traceability of calibration and calibration standards to nationally recognized standards (e.g., NIST), equivalent international standards or other acceptable measurement standards (intrinsic).	Commercial Grade Survey Or ILAC Accreditation in lieu of Commercial Grade Survey	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verify the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA.	Not Applicable Not Applicable	Calibration standards and reference materials are traceable to national, international, or intrinsic standards. Calibration standards and reference materials are traceable to national, international, or intrinsic standards where available.

ID	CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
2	Calibrations are performed in accordance with written procedures/instructions.	Commercial Grade Survey Or ILAC Accreditation in lieu of Commercial Grade Survey	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verify the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA.	Not Applicable Not Applicable	Adequate documented instructions exist for performance of accurate calibration. Adequate documented instructions exist for performance of accurate calibration.

SECTION I CRITICAL CHARACTERISTICS

ID	CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
3	Documented training/qualification of personnel.	Commercial Grade Survey Or ILAC Accreditation in lieu of Commercial Grade Survey	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verify the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA.	Not Applicable Not Applicable	Personnel have the adequate skills, training, and experience to ensure accurate and repeatable calibration. Personnel have the adequate skills, training, and experience to ensure accurate and repeatable calibration.

ID	CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
4	Environmental Conditions, e.g., temperature, humidity, vibration, etc.	Commercial Grade Survey Or ILAC Accreditation in lieu of Commercial Grade Survey	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verify the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA.	Not Applicable Not Applicable	The calibration environment is controlled to the extent necessary to ensure continued measurement with required accuracy on standards and measuring equipment. The calibration environment is controlled to the extent necessary to ensure continued measurement with required accuracy on standards and measuring equipment.

ID	CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
5	Adequacy, accuracy, stability, tolerances (uncertainty) and range of measurement standards	Commercial Grade Survey Or ILAC Accreditation in lieu of Commercial Grade Survey	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verify the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA	Not Applicable Not Applicable	The service provider's M&TE and standards have the needed accuracy, stability, tolerances (uncertainty) and range for the items being calibrated. The service provider's M&TE and standards have the needed accuracy, stability, tolerances (uncertainty) and range for the items being calibrated.

ID	CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
6	Intervals of calibration for standards	Commercial Grade Survey Or ILAC Accreditation in lieu of Commercial Grade Survey	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verify the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA.	Not Applicable Not Applicable	The service provider's calibration standards are calibrated at defined intervals The service provider's calibration standards are calibrated at defined intervals

ID	CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
7	Software control, e.g., adequate review/approval, verification, validation, error notification, etc.	Commercial Grade Survey Or ILAC Accreditation in lieu of Commercial Grade Survey	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verify the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA.	Not Applicable Not Applicable	The service provider has a process for performing validation/verification testing to ensure the software performs as intended and controlling the version level of the applicable software. The service provider has a process for performing validation/verification testing to ensure the software performs as intended and controlling the version level of the applicable software.

ID	CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
8	Calibration status	Commercial Grade Survey Or ILAC Accreditation in lieu of Commercial Grade Survey	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verify the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA.	Not Applicable Not Applicable	The service provider's M&TE and standards are uniquely identified and labeled to indicate calibration status. Items that are not calibrated to their full range, or have other limitations, are identified to that condition. The service provider's M&TE and standards are uniquely identified and labeled to indicate calibration status. Items that are not calibrated to their full range, or have other limitations, are identified to that condition.

ID	CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
9	Out of tolerance notification & corrective action	Commercial Grade Survey Or ILAC Accreditation in lieu of Commercial Grade Survey	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verify the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA.	Not Applicable Not Applicable	Service provider has an adequate notification process when the supplier's M&TE/standards are found to be out of tolerance to an extent that customer's calibration results may be impacted. Service provider has an adequate notification process when the supplier's M&TE/standards are found to be out of tolerance to an extent that customer's calibration results may be impacted.

ID	CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
10	Subcontractor calibration controls	Commercial Grade Survey Or ILAC Accreditation in lieu of Commercial Grade Survey	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verification the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA.	Not Applicable Not Applicable	Sub-suppliers providing calibration services for the service provider's M&TE and standards are capable of performing the required services with adequate quality. Sub-suppliers providing calibration services for the service provider's M&TE and standards are capable of performing the required services with adequate quality.
11	Calibration certification documentation	Commercial Grade Survey Or ILAC Accreditation in lieu of Commercial Grade Survey	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verify the service provider is accredited to ISO/IEC 17025:2005/2017 by an AB which is a signatory to the ILAC MRA	Not Applicable Not Applicable	The service provider submits the required certification documentation including certificates of calibration. The service provider submits the required certification documentation including certificates of calibration.

DESCRIPTION OF SAMPLING PLAN (if "see below" is selected in the sampling plan column above)

Not applicable

OTHER RELEVANT INFORMATION**Commercial Grade Surveys**

If a commercial grade survey is utilized to verify the laboratory controls the critical characteristics identified above, a survey report and checklist must be used to document the laboratory's control over the critical characteristics in accordance with applicable procedures.

ILAC Process

Through their endorsement of NEI 14-05A, the NRC determined that the ILAC process is an acceptable method for verification that a laboratory controls the above critical characteristics in lieu of a survey. Therefore, the above critical characteristics can be verified by performing a commercial grade survey, source verification, or by taking credit for the ILAC process. The ILAC process requires verification that a laboratory is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) along with the following:

1. A documented review of the supplier's accreditation is performed and includes a verification of the following:
 - a. The calibration laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025:2005/20052017, "General Requirements for the Competence of Testing and Calibration Laboratories."
 - b. The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
2. The purchase documents require that:
 - a. The service must be provided in accordance with their accredited ISO/IEC-17025:2005/2017:2005 program and scope of accreditation.
 - b. As-found calibration data must be reported in the certificate of calibration when calibrated items are found to be out-of-tolerance.
 - c. The equipment/standards used to perform the calibration must be identified in the certificate of calibration.
 - d. Subcontracting of this accredited services is prohibited.

OTHER RELEVANT INFORMATION

- e. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
 - f. Additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.
3. It is validated, at receipt inspection, that the laboratory's documentation certifies that:
- a. The contracted calibration service has been performed in accordance with their ISO/IEC-17025:2005/2017:2005 program, and has been performed within their scope of accreditation.
 - b. The purchase order's requirements are met.

Successful completion of the receiving activities, along with a supplier certificate of calibration and certification attesting that the calibration service provided has been performed in accordance with the laboratory's ISO/IEC-17025:2005/2017 program and within the laboratory's scope of accreditation, provides reasonable assurance that the calibration service provided will not adversely impact the safety function of associated plant equipment that is calibrated or tested using the subject M&TE item.

BASIS FOR SELECTION OF SAMPLING PLANS (IF SAMPLING PLANS ARE USED)

Not Applicable

SECTION J REFERENCES

DOCUMENT / SOURCE	REVISION / DATE	COMMENTS
[Enter Company's Name] Quality Program Manual or Procedure		This document provides the requirements for accepting commercial services without conducting a commercial grade survey.
NEI 14-05A "Guidelines for the use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services"	Rev. 1	This document provides guidance to an acceptable approach for procuring commercial grade calibration by laboratories accredited by International Laboratory Accreditation Cooperation (ILAC) signatories.
Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related	EPRI 3002002982, Revision 1 to EPRI	This document provides guidance for the dedication of commercial grade dedicated services.

DOCUMENT / SOURCE	REVISION / DATE	COMMENTS
Applications	NP-5652 and TR-102260/9-2014	

SECTION K REVIEW AND APPROVAL

Prepared By:

Date

Reviewed By:

Date

Example Only

SECTION A ITEM/SERVICE DESCRIPTION – TESTING SERVICES

This Technical Evaluation addresses laboratory testing services from commercial testing service providers including ISO/IEC 17025:2005/2017 accredited laboratories and non-accredited service providers. It provides the Commercial Grade Item (CGI) dedication requirements for commercial testing services. The critical characteristics are the same whether one verifies the critical characteristics via a commercial grade survey or takes credit for the laboratory being accredited to ISO/IEC 17025:2005/2017 as detailed in NEI 14-05A. NEI 14-05A has been endorsed by the US NRC and allows the dedicating entity to take credit for verification of the critical characteristics by virtue of the laboratory being accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body (AB) which is signatory the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). This process can be used in lieu of performing a commercial grade survey to verify the laboratory's control over the critical characteristics. This evaluation also covers laboratory testing services from various disciplines including chemical, mechanical, metallurgical, etc.

SECTION B END USE / PARENT / HOST EQUIPMENT INFORMATION

Note: If the specific end-use(s) / plant applications are not known, complete Section C of this form in lieu of Section B prior to proceeding.

Not Applicable (Section C Completed Below)

EQUIPMENT ID (TAG) NUMBERS OR DESCRIPTION OF ITEM/SERVICE USAGE:**PARENT COMPONENT/HOST DESCRIPTION:****FUNCTIONAL SAFETY CLASS OF COMPONENT / HOST:**

- Safety-Related
 Non-Safety Related (If non-safety, item/service is not a candidate for dedication)

BASIS / SOURCE:**IDENTIFICATION OF PARENT COMPONENT/HOST EQUIPMENT FUNCTION(S)**

FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
<input type="checkbox"/> Active <input type="checkbox"/> Passive		

PARENT COMPONENT/HOST EQUIPMENT IS (CHECK ALL THAT APPLY):

- EQ
 CLASS 1E
 SEISMIC CLASS 1
 OTHER: (see below)
- ASME SECTION III
 CONTAINMENT PRESSURE BOUNDARY
 SERVICE LEVEL 1 COATING

SECTION C BOUNDED SCOPE OF USE

Only complete Section C when specific end-use of the item/service being dedicated is unknown.

Not Applicable (Section B Completed Above)

Is the item/service being dedicated a commodity or standard item/service designed and constructed in accordance with an industry standard?

Yes
 No

IF "YES", LIST THE STANDARD(S) BELOW

ISO/IEC 17025:2005/2017, "General Requirements for the Competence of Testing and Calibration Laboratories."

LIST FUNCTIONS AND/OR APPLICATIONS CONSIDERED WHEN COMPLETING THIS EVALUATION

Test results and data provided may be used in accordance with the [Enter Company Name] 10CFR50 Appendix B QA program to verify the acceptability of an item or specific critical characteristics of an item for use as a basic component and its ability to perform its safety-related design functions.

The basic safety function of testing is to verify the acceptability of a single critical characteristic or multiple critical characteristics which supports the safety function of a items which will be dedicated as a basic component. For instance, a commercial testing service can be used to verify the material of construction of a fasteners which is being dedicated for use as a basic component.

This TE addresses commercial testing services including those supplied by providers under an ISO/IEC 17025:2005/2017 accreditation and those supplied by a provider that is not accredited.

EQUIPMENT QUALIFICATION CONSIDERATIONS / LIMITATIONS (CHECK ALL THAT APPLY):**CONSIDERATION**

QUALIFICATION BASIS / LIMITATIONS OF USE: Not applicable. While testing services can be used to verify one or more critical characteristics associated with environmental or seismic qualification, the testing service itself is not being environmentally or seismically qualified.

- ENVIRONMENTAL QUALIFICATION
 SEISMIC QUALIFICATION
 OTHER: (see below)

SECTION D SERVICE INFORMATION

ITEM/SERVICE DESCRIPTION:

This technical evaluation covers the commercial grade dedication for the commercial testing services including mechanical, electrical, chemical, metallurgical, etc. A separate technical evaluation is therefore not needed for each type of testing service since the critical characteristics all testing services are the same.

FUNCTIONAL SAFETY CLASS OF ITEM/SERVICE:

- Safety-Related
 Non-Safety Related (If non-safety, item/service is not a candidate for dedication)

BASIS / SOURCE:

The basic safety function of testing is to verify the acceptability of a single critical characteristic or multiple critical characteristics which supports the safety function of a items which will be dedicated as a basic component. For instance, a commercial testing service can be used to verify the material of construction for a fasteners which is being dedicated for use as a basic component.

IDENTIFICATION OF ITEM/SERVICE FUNCTION(S)

FUNCTIONAL MODE	BASIC SAFETY FUNCTION(S)	DESCRIBE (AS REQUIRED)
<input checked="" type="checkbox"/> Active <input checked="" type="checkbox"/> Passive	<p>The safety function of testing is to verify the acceptability of a single critical characteristic or multiple critical characteristics which supports the safety function of a item which will be dedicated for use as a basic component. For instance, a commercial testing service can be used to verify the material of construction of a fastener which is being dedicated for use as a basic component.</p>	<p>Testing services performed by commercial suppliers on behalf of [Enter Company Name] must be controlled in accordance with the [Enter Company Name] 10CFR50, Appendix B-compliant QA program. Test results may be used in accordance with the [Enter Company Name] 10CFR50 Appendix B QA program to verify the acceptability of a critical characteristic of an item being dedicated for use as a basic component.</p>

ITEM/SERVICE IS (CHECK ALL THAT APPLY):

- EQ
 CLASS 1E
 SEISMIC CLASS 1
 OTHER: (see below)
- ASME SECTION III
 CONTAINMENT PRESSURE BOUNDARY
 SERVICE LEVEL 1 COATING

SECTION E ELIGIBILITY FOR DEDICATION

Is the item/service eligible for dedication in accordance with 10CFR, Part 21?

Yes No

If the answer is no, this item/service cannot be dedicated.

SECTION F FAILURE MODES / MECHANISMS AND EFFECTS ANALYSIS

CREDIBLE FAILURE MODE/MECHANISM	EFFECTS ON SYSTEM/COMPONENT FUNCTION
<p>Failure Modes/Mechanisms and Effects Analysis is normally performed to help determine the critical characteristics. In the case of testing services, the critical characteristics are known as specified in NEI 14-05A. Therefore, a FMEA is not required.</p>	<p>Failure Modes/Mechanisms and Effects Analysis is normally performed to help determine the critical characteristics. In the case of testing services, the critical characteristics are known as specified in NEI 14-05A. Therefore, a FMEA is not required.</p>
BASIS FOR SELECTION OF CREDIBLE FAILURE MODE(S)/MECHANISM(S)	
<p>Failure Modes/Mechanisms and Effects Analysis is normally performed to help determine the critical characteristics. In the case of testing services, the critical characteristics are known as specified in NEI 14-05A. Therefore, a FMEA is not required.</p>	

SECTION G OPERATING EXPERIENCE / HISTORICAL PERFORMANCE INFORMATION

SOURCES REVIEWED AND RESULTS

External – An INPO OE search was conducted using the terms “testing lab”, “vendor testing”, “dedication testing”, “testing cgi”, and “testing service”. There was no information identified.

Internal – Include any Internal Operating Experience

SECTION H IDENTIFICATION ATTRIBUTES

IDENTIFICATION ATTRIBUTES	DESCRIPTION OF INSPECTION	ACCEPTANCE CRITERIA
Testing service provider	Visual	The testing service provider is as specified in the purchasing document for the testing service performed.
Test Specimen	Visual	The item to be tested has the same identification number as the one specified in the purchasing document for the testing service.

SECTION I CRITICAL CHARACTERISTICS

ID	CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
1	Identification/traceability of the item during testing/and processing is maintained.	Commercial Grade Survey Or ILAC Accreditation in lieu of Survey Commercial Grade Source Verification	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verify the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA	Not Applicable Not Applicable	The testing lab has a process for maintaining the identification and traceability of the test specimen. The testing lab has a process for maintaining the identification and traceability of the test specimen.
2	Testing for the required characteristics/parameters is performed in accordance with written industry recognized standards or other validated and approved test methods.	Commercial Grade Survey Or ILAC Accreditation in lieu of Survey Commercial Grade Source Verification	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verify the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA	Not Applicable Not Applicable	Adequate documented instructions exist for performance of testing based on internally or externally validated methodology Adequate documented instructions exist for performance of testing based on internally or externally validated methodology

SECTION I CRITICAL CHARACTERISTICS

ID	CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
3	Actual testing is performed in accordance with written and approved procedures.	Commercial Grade Survey Or ILAC Accreditation in lieu of Survey Commercial Grade Source Verification	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verification the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA	Not Applicable Not Applicable	Testing is performed in accordance with approved procedures and instructions Testing is performed in accordance with approved procedures and instructions
4	Testing is performed by trained and qualified personnel.	Commercial Grade Survey Or ILAC Accreditation in lieu of Survey Commercial Grade Source Verification	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verification the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA	Not Applicable Not Applicable	Laboratory has a documented process for the training and qualification of personnel and performing the testing have been approved to perform the testing in accordance with the quality program. Laboratory has a documented process for the training and qualification of personnel and performing the testing have been approved to perform the testing in accordance with the quality program.

ID	CRITICAL CHARACTERISTICS	ACCEPTANCE METHOD	DESCRIPTION OF ACCEPTANCE ACTIVITY	SAMPLING PLAN	ACCEPTANCE CRITERIA (INCLUDING TOLERANCES)
5	M&TE including chemical standards are calibrated as applicable and are traceable to national, international, or intrinsic properties/natural law.	Commercial Grade Survey Or ILAC Accreditation in lieu of Survey Commercial Grade Source Verification	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verification the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA	Not Applicable Not Applicable	The service provider's M&TE and standards have the needed accuracy, stability, tolerances (uncertainty) and range for the items being calibrated. The service provider's M&TE and standards have the needed accuracy, stability, tolerances (uncertainty) and range for the items being calibrated.
6	Traceability of the test results to the item being tested is maintained.	Commercial Grade Survey Or ILAC Accreditation in lieu of Survey Commercial Grade Source Verification	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verification the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA	Not Applicable Not Applicable	
7	Certification includes test results, identification of the item, test method used, results, and signature of responsible laboratory authority	Commercial Grade Survey Or ILAC Accreditation in lieu of Survey Commercial Grade Source Verification	Perform Commercial Grade Survey to verify the service provider adequately controls this CC. Verify the service provider is accredited to ISO/IEC 17025:2005/2017 by an Accreditation Body which is a signatory to the ILAC MRA	Not Applicable Not Applicable	

DESCRIPTION OF SAMPLING PLAN (if “see below” is selected in the sampling plan column above)

Not applicable

OTHER RELEVANT INFORMATION**Commercial Grade Surveys**

If the a commercial grade survey is utilized to verify the laboratory controls the critical characteristics identified above, a survey report and checklist must be used to document the laboratory's control over the critical characteristics in accordance with applicable procedures.

Commercial Grade Source Verifications

If a commercial grade source verification is utilized to verify the laboratory controls the critical characteristics identified above, the source verification must be performed for each item calibrated by the laboratory. Sampling is not permitted. In addition, a report and checklist must be used to document the laboratory's control over the critical characteristics in accordance with applicable procedures.

ILAC Process

Through their endorsement of NEI 14-05A, the NRC determined that the ILAC process is an acceptable method for verification that a laboratory controls the above critical characteristics in lieu of a survey. Therefore, the above critical characteristics can be verified by performing a commercial grade survey, source verification, or by taking credit for the ILAC process. The ILAC process requires verification that a laboratory is accredited to ISO/IEC 17025:2005/2017 by and Accreditation Body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) along with the following: .

1. A documented review of the supplier's accreditation is performed and includes a verification of the following:
 - a. The testing laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025:2005/:20052017, "General Requirements for the Competence of Testing and Calibration Laboratories"
 - b. The published scope of accreditation for the testing laboratory covers the needed testing services including test methodology and tolerances/uncertainty.
2. The purchase documents require that:
 - a. The service must be provided in accordance with their accredited ISO/IEC-17025:2005/2017:2005 program and scope of accreditation.
 - b. The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
 - c. Subcontracting of this accredited services is prohibited.
 - d. Additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include, but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.
3. It is validated, at receipt inspection, that the laboratory's documentation certifies that:
 - a. The contracted testing service has been performed in accordance with their ISO/IEC-17025:2005/2017:2005 program, and has been performed within their scope of accreditation, and
 - b. The purchase order's requirements are met.

OTHER RELEVANT INFORMATION

Successful completion of the receiving activities, along with a supplier test report and certification attesting that the testing service provided has been performed in accordance with the laboratory's ISO/IEC-17025:2005/2017 program and within the laboratory's scope of accreditation, provides reasonable assurance that the testing service provided will not adversely impact the safety function of item associated with the testing.

BASIS FOR SELECTION OF SAMPLING PLANS (IF SAMPLING PLANS ARE USED)

Not Applicable

SECTION J REFERENCES

DOCUMENT / SOURCE	REVISION / DATE	COMMENTS
[Enter Company's Name] Quality Program Manual or Procedure		This document provides the requirements for accepting commercial services without conducting a commercial grade survey.
NEI 14-05A "Guidelines for the use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services"	Rev. 1	This document provides guidance to an acceptable approach for procuring commercial grade testing services by laboratories accredited by International Laboratory Accreditation Cooperation (ILAC) signatories.
Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications	EPRI 3002002982, Revision 1 to EPRI NP-5652 and TR-102260/9-2014	This document provides guidance for the dedication of commercial grade dedicated services.

SECTION K REVIEW AND APPROVAL

Prepared By:

Date

Reviewed By:

Date

Fields, Leslie

To: mar@nei.org
Cc: Kavanagh, Kerri; Park, Dong; Morey, Dennis; Diaz-Castillo, Yamir
Subject: Request for Additional Information for NEI 14-05A Revision 1

Dear Mr. Richter of the Nuclear Energy Institute:

I have placed an electronic version of this Request for Additional Information (RAI) for NEI 14-05 A, Revision 1, "Guidelines for the use of Accreditation In Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," in the BOX.com folder and have given you access to it. This email serves as the formal transmittal of this RAI.

The RAI has been placed in ADAMS as nonpublic so it can be declared an Official Agency Record. When responding to the RAI, please confirm if there is any proprietary information in the RAI and the response. Your formal response, provided via letter under authorized signature, will generate the public version of the RAI as well as the response.

In order to support the staff's review schedule, please provide your response no later than May 15, 2020.

If you have any questions or would like to discuss the RAI with staff to ensure you understand them, please let me know.

This email will be uploaded in ADAMS and declared public in a couple days.

Leslie Fields, Senior Project Manager
U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation
301-415-1186
leslie.fields@nrc.gov

Transmittal of NRC's Request for Additional Information Associated with NEI 14-05A, Revision 1, "Guidelines for the use of Accreditation In Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services"

RAI – 01 - Section 3.4, "Limitations of Use," states, in part, that the International Laboratory Accreditation Cooperation (ILAC) accreditation process cannot be used for the commercial-grade dedication of non-destructive examination (NDE) services based on the laboratory's ISO/IEC 17025:2017 accreditation due to there being specific personnel qualification and certification requirements for personnel performing NDE activities for the nuclear industry that may not be addressed during the accreditation process.

In addition, Section 4, "Purchaser's Quality Assurance Program," states, in part, that "A template for describing the use of the ILAC process in lieu of a commercial grade survey in a purchaser's QA Program is provided in Appendix A. Although a purchaser is not required to use the template in Appendix A, all of the actions and steps described in Appendix A need to be included in the purchaser's QA Program."

The NRC staff noted that the prohibition of using the ILAC accreditation process for the commercial-grade dedication of NDE services is not part of the template in Appendix A, "Quality Assurance Program Template." Although not mandatory, a licensee or a vendor may elect to implement the template without incorporating this requirement.

In order to avoid any confusion, the template in Appendix A should be updated to clearly state that the ILAC accreditation process may not be used for the commercial-grade dedication of NDE services. NEI should submit updated information to address NRC's comments per this request.

MARK A. RICHTER, PH.D.

*Senior Project Manager,
Used Fuel and Decommissioning Programs*

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mar@nei.org
nei.org



May 13, 2020

Ms. Leslie Fields
Senior Project Manager
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Submittal of Response to Request for Additional Information (RAI) for NEI 14-05A, Revision 1, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services"

Project Number: 689

Dear Ms. Fields:

On May 1, 2020,¹ the U.S. Nuclear Regulatory Commission (NRC) requested additional information to continue portions of its review of NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services, Revision 1."² This revised guidance provides an approach to utilize accreditation by signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) as part of a purchaser's commercial grade dedication of laboratory services.

On behalf of the nuclear energy industry, the Nuclear Energy Institute (NEI)³ submits this response to the NRC's request for additional information (RAI) and a mark-up of NEI 14-05A Revision 1 that reflect updates in response to the RAI. We believe that this response will allow the NRC to complete its review and endorse the revised guidance as an acceptable method for continuing the use of accreditation by ILAC MRA

¹ Email from Leslie Fields (NRC) to Mark Richter (NEI), "Request for Additional Information for NEI 14-05A Revision 1," May 1, 2020, ADAMS ML20121A319.

² M. A. Richter (NEI) letter to K. A. Kavanagh (NRC), "Submittal of NEI 14-05A, Revision 1, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," February 20, 2020 (ADAMS ML20054C066.

³ The Nuclear Energy Institute (NEI) is responsible for establishing unified policy on behalf of its members relating to matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect and engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations involved in the nuclear energy industry.

Ms. Leslie Fields

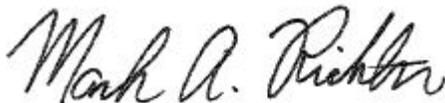
May 13, 2020

Page 2

signatories in lieu of commercial grade surveys. Three additional clarifications were made to the document that are considered to be inconsequential to receiving the NRC's endorsement. All changes are described in the attached response.

We appreciate the NRC's consideration of the guidance and look forward to a timely endorsement. If you have any questions or require additional information, please contact me.

Sincerely,

A handwritten signature in black ink that reads "Mark A. Richter". The signature is written in a cursive, flowing style.

Mark A. Richter

Attachments (2)

c: Ms. Kerri Kavanagh, Chief, NRC/NRR/MVIB
Mr. Yamir Diaz-Castillo, NRC /NRR/MVIB
Mr. Dong Park, NRC/NRR/MVIB
Mr. Dennis Morey, NRC/NRR/ORL
Mr. Earl Mayhorn, NUPIC/Ameren
NRC Document Control Desk

NEI's response to the question contained in the May 1, 2020 email titled: "Transmittal of NRC's Request for Additional Information Associated with NEI 14-05A, Revision 1, "Guidelines for the use of Accreditation In Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," follows below. The changes indicated in the response are included in the update to Revision 1 of NEI 14-05A attached.

NRC RAI – 01 – NEI 14-05A

Section 3.4, "Limitations of Use," states, in part, that the International Laboratory Accreditation Cooperation (ILAC) accreditation process cannot be used for the commercial-grade dedication of nondestructive examination (NDE) services based on the laboratory's ISO/IEC 17025:2017 accreditation due to there being specific personnel qualification and certification requirements for personnel performing NDE activities for the nuclear industry that may not be addressed during the accreditation process.

In addition, Section 4, "Purchaser's Quality Assurance Program," states, in part, that "A template for describing the use of the ILAC process in lieu of a commercial grade survey in a purchaser's QA Program is provided in Appendix A. Although a purchaser is not required to use the template in Appendix A, all of the actions and steps described in Appendix A need to be included in the purchaser's QA Program."

The NRC staff noted that the prohibition of using the ILAC accreditation process for the commercial-grade dedication of NDE services is not part of the template in Appendix A, "Quality Assurance Program Template." Although not mandatory, a licensee or a vendor may elect to implement the template without incorporating this requirement.

In order to avoid any confusion, the template in Appendix A should be updated to clearly state that the ILAC accreditation process may not be used for the commercial-grade dedication of NDE services. NEI should submit updated information to address NRC's comments per this request.

NEI Response

The NEI ILAC Task Force has reviewed the NRC's Request for Additional Information (RAI) and agrees that Appendix A should be updated to clarify that the ILAC accreditation process described in NEI 14-05A may not be used for the commercial grade dedication of NDE services. As noted in the RAI, Section 3.4 of NEI 14-05A, Rev. 1 clearly indicates this point. Therefore, for consistency and clarity, Appendix A has been updated by adding the following statement: "As discussed in Section 3.4 of this document, NEI 14-05A cannot be used to dedicate NDE services (including ASME Code and non-Code safety related applications) in lieu of a commercial grade survey."

In addition, Appendix A has been updated to clearly indicate that a commercial grade dedication technical evaluation is required to document the critical characteristics and acceptance methods when dedicating calibration and testing services based on the ILAC Process. Attachment 1 and Attachment 2 of

NEI 14-05A include acceptable examples of a technical evaluation for calibration services and testing services, respectively.

Two other inconsequential updates were made:

1. NEI 14-05A, Section 2.2, "DESCRIPTION OF THE REGIONAL ORGANIZATIONS" was updated to indicate there are now five (5) regional cooperation bodies within ILAC instead of three (3). The current regional bodies include: Asian Pacific Accreditation Cooperation (APAC), African Accreditation Cooperation (AFRAC), Arab Accreditation Cooperation (ARAC), European Accreditation (EA), and Inter-American Accreditation Cooperation (IAAC). The addition of two regional cooperation bodies has no impact on the ILAC process utilized to dedicate calibration and testing services based on accreditation to ISO/IEC 17025:2017.
2. Appendix A was updated to reference Regulatory Guide 1.164¹ and the latest NRC-endorsed commercial grade dedication guidance (EPRI TR-3002002982²). EPRI TR-3002002982 is referenced in other sections of this document.

¹ U.S. Nuclear Regulatory Commission Regulatory Guide 1.164, "Dedication of Commercial-Grade Items for Use in Nuclear Power Plants," Revision 0, July 2017 (ADAMS ML17041A206).

² Electric Power Research Institute (EPRI) Technical Report 3002002982, "Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications," Revision 1, September 2014 (ADAMS ML181999A161)

Fields, Leslie

To: mar@nei.org
Cc: Kavanagh, Kerri; Morey, Dennis; Diaz-Castillo, Yamir; Park, Dong
Subject: Request for Additional Information (RAI) for NEI 14-05A, Revision 1

Dear Mr. Richter of the Nuclear Energy Institute:

With respect to NEI 14-05 A, Revision 1, "Guidelines for the use of Accreditation In Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," enclosed below you will find additional Requests for Additional Information (RAI).

This email serves as the formal transmittal for these RAIs. Your formal response, provided via email/letter under authorized signature, will generate the public version of the RAI response. Please confirm if there is any proprietary information in the RAI response for future processing.

In order to support the NRC staff's review schedule, please provide your response no later than July 20, 2020.

Let me know if you have any questions or would like to discuss the RAIs with NRC staff to ensure you understand the NRC request.

A copy of this email and RAIs will be uploaded in ADAMS and declared publicly available.

NRC'S REQUEST FOR ADDITIONAL INFORMATION

ASSOCIATED WITH NEI 14-05 A, REVISION 1, "GUIDELINES FOR THE USE OF ACCREDITATION IN LIEU OF COMMERCIAL GRADE SURVEYS FOR PROCUREMENT OF LABORATORY CALIBRATION AND TEST SERVICES"

PROJECT NO. 689

By letter dated February 20, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20034F042), the Nuclear Energy Institute (NEI) submitted Revision 1 of NEI 14-05 A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," to the U.S. Nuclear Regulatory Commission (NRC) for NRC staff review and approval. To complete its review, the NRC staff has the following questions it would like NEI to address.

RAI 02 - Section 1.3, "Acceptance of Accreditation by ILAC Signatories in Lieu of Commercial Grade Surveys"

Section 1.3 states, in part, that "ISO/IEC 17025:2017 was released on November 30, 2017. During the three year transition period, both ISO/IEC 17025:2005 and ISO/IEC 17025:2017 are valid. After November 30, 2020, ISO/IEC 17025:2005 will become invalid and only accreditation to ISO/IEC 17025:2017 can be achieved and recognized under the ILAC MRA process. Therefore, this document recognizes accreditation to ISO/IEC 17025:2005 through November 30, 2020."

As result of the ongoing Coronavirus Disease 2019 (COVID-19) pandemic, ILAC extended the transition period for ISO/IEC 17025:2017 from November 30, 2020 to June 1, 2021.

In light of ILAC's extension of the transition period, please clarify if Revision 1 of NEI 14-05 A also recognizes June 1, 2021 as an acceptable date for laboratories to transition to ISO/IEC 17025:2017.

RAI 03 - Section 5.2, "Verification That the ILAC Process Continues to be Consistent with NRC Accepted Practices"

Section 5.2 states, in part, that "The assessments and conclusions of the rigor of the ILAC process documented herein are based in large part on the evaluation of the ILAC requirements and procedures. The comparison of ILAC requirements and procedures, in particular standard ISO/IEC 17025:2017, to NRC requirements, NRC endorsed guidance, and NUPIC checklists, which conform to these requirements and guidance, is the primary basis for the approach documented within to use the ILAC process in lieu of a commercial grade survey. As part of the continued oversight, the nuclear industry (NEI, NUPIC members, and other industry representatives) will monitor the ILAC requirements and procedures to verify that they continue to be consistent with NRC accepted practices."

Due to the ongoing COVID-19 pandemic, the NRC staff recently learned that accrediting bodies are currently performing renewal assessments remotely. This is not a position the NRC staff has had the opportunity to evaluate and determine to be an acceptable approach for performing renewal assessments. The NRC's recognition of the ILAC accreditation process allows licensees and vendors to take credit for the ILAC accreditation process in lieu of performing an *on-site* commercial-grade survey as part of the commercial-grade dedication process of calibration and testing services. In its initial recognition of the ILAC accreditation process, the NRC staff determined that as part of the on-site renewal assessments performed by the accrediting bodies, the critical characteristics for calibration and testing services would be verified as part of the on-site renewal assessment. Given that these renewal assessments are now being done remotely:

- a. Please clarify if NEI has considered how these remote assessments still provide the same degree of confidence to determine that the laboratories are adequately implementing the requirements of ISO/IEC 17025.
- b. As part of its continued oversight, please explain how the nuclear industry (NEI, NUPIC members, and other industry representatives) will effectively monitor the implementation of the ILAC accreditation process to verify that it continues to be consistent with NRC's accepted practices.

MARK A. RICHTER, PH.D.
*Senior Project Manager,
Used Fuel and Decommissioning*

1201 F Street, NW, Suite 1100
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P: 202.739.8106
mar@nei.org
nei.org



September 11, 2020

Ms. Leslie Fields
Senior Project Manager
U.S. Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation
Washington, DC 20555-0001

Subject: Submittal of Response to Request for Additional Information (RAI) for NEI 14-05A, Revision 1, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services"

Project Number: 689

Dear Ms. Fields:

On July 6, 2020,¹ the U.S. Nuclear Regulatory Commission (NRC) issued a second round of Requests for Additional Information (RAIs) in order to continue portions of its review of NEI 14-05A, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," Revision 1.² This revised guidance provides an approach to utilize accreditation by signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) as part of a purchaser's commercial grade dedication of laboratory services.

On behalf of the nuclear energy industry, the Nuclear Energy Institute (NEI)³ submits the attached responses to the NRC's RAIs and a mark-up of NEI 14-05A Revision 1 that reflect updates in response to the RAI's. We believe that these responses will allow the NRC to complete its review and endorse the revised

¹ Email from Leslie Fields (NRC) to Mark Richter (NEI), "Request for Additional Information for NEI 14-05A Revision 1," July 6, 2020, ADAMS ML20184A288.

² M. A. Richter (NEI) letter to K. A. Kavanagh (NRC), "Submittal of NEI 14-05A, Revision 1, "Guidelines for the Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services," February 20, 2020 (ADAMS ML20054C066.)

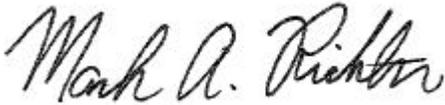
³ The Nuclear Energy Institute (NEI) is responsible for establishing unified policy on behalf of its members relating to matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect and engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations involved in the nuclear energy industry.

Ms. Leslie Fields
September 11, 2020
Page 2

guidance as an acceptable method for continuing the use of accreditation by ILAC MRA signatories in lieu of commercial grade surveys. All changes are described in the attached response.

We appreciate the NRC's consideration of the guidance and look forward to a timely endorsement. If you have any questions or require additional information, please contact me.

Sincerely,

A handwritten signature in black ink that reads "Mark A. Richter". The signature is written in a cursive style with a large, prominent "M" and "R".

Mark A. Richter

Attachments

c: Ms. Kerri Kavanagh, Chief, NRC/NRR/MVIB
Mr. Yamir Diaz-Castillo, NRC /NRR/MVIB
Mr. Dong Park, NRC/NRR/MVIB
Mr. Dennis Morey, NRC
Mr. Earl Mayhorn, NUPIC/Ameren
NRC Document Control Desk

NEI's response to the questions contained in the July 6, 2020 letter titled "2nd Round - Request for Additional Information Associated with NEI 14-05A, Revision 1, "Guidelines for the use of Accreditation In Lieu of Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services." The changes indicated in the response are included in the update to Revision 1 of NEI 14-05A.

NRC RAI – 02 – NEI 14-05A - Section 1.3, "Acceptance of Accreditation by ILAC Signatories in Lieu of Commercial Grade Surveys"

Section 1.3 states, in part, that "ISO/IEC 17025:2017 was released on November 30, 2017. During the three-year transition period, both ISO/IEC 17025:2005 and ISO/IEC 17025:2017 are valid. After November 30, 2020, ISO/IEC 17025:2005 will become invalid and only accreditation to ISO/IEC 17025:2017 can be achieved and recognized under the ILAC MRA process. Therefore, this document recognizes accreditation to ISO/IEC 17025:2005 through November 30, 2020."

As result of the ongoing Coronavirus Disease 2019 (COVID-19) pandemic, ILAC extended the transition period for ISO/IEC 17025:2017 from November 30, 2020 to June 1, 2021.

In light of ILAC's extension of the transition period, please clarify if Revision 1 of NEI 14-05 A also recognizes June 1, 2021 as an acceptable date for laboratories to transition to ISO/IEC 17025:2017.

NEI Response

At the time of the original submittal of Revision 1 of NEI 14-05A, the current global COVID-19 pandemic had not been declared. In June 2020, ILAC decided to extend the end of the ISO/IEC 17025:2017 transition period from November 30, 2020 to June 1, 2021 to ensure all laboratories can be transitioned following the restrictions imposed as a result of the global COVID-19 outbreak. Likewise, Section 1.3 of NEI 14-05A has been updated to recognize both ISO/IEC 17025:2005 and ISO/IEC 17025:2017 through June 1, 2021. After June 1, 2021, ISO/IEC 17025:2005 will no longer be valid and only accreditation to ISO/IEC 17025:2017 will be achievable and recognized by ILAC. The NRC has previously provisionally endorsed ISO/IEC 17025:2017. In addition, due to the extension of the transition period, the new limitations for the use of the ILAC Process regarding subcontracting calibrations/testing and Non-Destructive Examination (NDE) services will not go into effect until June 2, 2021.

NEI RAI 03 – NEI 14-05A - Section 5.2, “Verification That the ILAC Process Continues to be Consistent with NRC Accepted Practices”

Section 5.2 states, in part, that “The assessments and conclusions of the rigor of the ILAC process documented herein are based in large part on the evaluation of the ILAC requirements and procedures. The comparison of ILAC requirements and procedures, in particular standard ISO/IEC 17025:2017, to NRC requirements, NRC endorsed guidance, and NUPIC checklists, which conform to these requirements and guidance, is the primary basis for the approach documented within to use the ILAC process in lieu of a commercial grade survey. As part of the continued oversight, the nuclear industry (NEI, NUPIC members, and other industry representatives) will monitor the ILAC requirements and procedures to verify that they continue to be consistent with NRC accepted practices.”

Due to the ongoing COVID-19 pandemic, the NRC staff recently learned that accrediting bodies are currently performing renewal assessments remotely. This is not a position the NRC staff has had the opportunity to evaluate and determine to be an acceptable approach for performing renewal assessments. The NRC’s recognition of the ILAC accreditation process allows licensees and vendors to take credit for the ILAC accreditation process in lieu of performing an on-site commercial-grade survey as part of the commercial-grade dedication process of calibration and testing services. In its initial recognition of the ILAC accreditation process, the NRC staff determined that as part of the on-site renewal assessments performed by the accrediting bodies, the critical characteristics for calibration and testing services would be verified as part of the on-site renewal assessment. Given that these renewal assessments are now being done remotely:

a. Please clarify if NEI has considered how these remote assessments still provide the same degree of confidence to determine that the laboratories are adequately implementing the requirements of ISO/IEC 17025.

b. As part of its continued oversight, please explain how the nuclear industry (NEI, NUPIC members, and other industry representatives) will effectively monitor the implementation of the ILAC accreditation process to verify that it continues to be consistent with NRC’s accepted practices.

NEI Response to Part A

While ISO/IEC 17025 outlines the requirements that accredited calibration and testing laboratories must meet, ISO/IEC 17011-2017, "Conformity assessment — Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies," includes the requirement that Accreditation Bodies (ABs) must meet for accrediting laboratories. Section 7.9.3 of ISO/IEC 17011:2017 indicates, in part, that the time between consecutive on-site assessments shall not exceed two years. However, if the accreditation body determines that an on-site assessment is not applicable, it shall use another assessment technique to achieve the same objective as the on-site assessment being replaced and justify the use of techniques such as a remote assessment. The term remote assessment was not included in previous versions of ISO/IEC 17011 and was added to the ISO/IEC 17011:2017. Remote assessment is defined in ISO/IEC 17011 as assessment of the physical location or virtual site of a conformity assessment body using

electronic means. Due to travel restrictions caused by the current COVID-19 pandemic, ABs are now exercising the option of performing remote accreditation assessments to maintain laboratories' accreditations. This practice was not identified by the industry during our 2017 observation of the Peer Evaluation of ATS- Serbia nor earlier observations such as the 2014 observation of the American Association for Laboratory Accreditation (A2LA) or the 2013 observation of the Japanese Accreditation Board (JAB). The industry's conclusion that accreditation assessments performed by ABs are essentially equivalent to NUPIC style commercial grade surveys was based on the accreditation assessments being performed on-site at the laboratory undergoing accreditation. Currently, NUPIC commercial grade surveys are required to be performed at the supplier's facility.

After receipt of this RAI, the industry researched this issue by contacting both ABs and laboratories to understand how remote assessments are being applied and to verify the integrity of the accreditation process is maintained which is strictly required by ISO/IEC 17011 regardless of the assessment technique employed. Due to the COVID-19 Pandemic, ABs are exercising the option of performing remote assessments to varying degrees including reaccreditation assessments, mid-term surveillances, and to a lesser extent, initial accreditation assessments. There have been no examples identified for which an initial accreditation assessment was performed for a laboratory performing testing/calibration for nuclear customers.

Based on information provided by US based ABs, currently there is no ILAC guidance or procedure for performing remote assessments. However, these ABs have controls in place which include the development of remote assessment guidelines; performance of risk assessments on a case by case basis to determine if a laboratory can be assessed remotely; management approval on a case by case basis; a requirement to document the justification for a remote assessment; and training of assessors prior to performing the assessment. In addition, we were informed that ILAC regional bodies such as APAC, IAAC, and EA are working to develop guidance for their regional ABs which should be available in Fall 2020.

While all ABs and laboratories contacted generally agreed that remote accreditation assessments have been an effective and useful tool to maintain accreditations during COVID-19 and during mid-term surveillance assessments, on-site assessment are preferred and there are no plans to replace on-site assessments going forward. These remote assessments are being employed to maintain the accreditation of laboratories and protect the health of laboratory and AB personnel with plans to resume on-site assessments as soon health conditions allow. In addition, ABs are motivated to maintain the integrity of the accreditation process. This is evident by the extension of the ISO/IEC 17025:2017 transition period to June 1, 2021 rather than relying on remote assessments alone. However, from an economic standpoint, the industry recognizes there will be some that will attempt to broaden the use of remote assessments after the global pandemic is over.

Next, the industry compared the practices of ABs during the pandemic with what is being done by the nuclear industry during the pandemic to maintain the qualification of suppliers. When NUPIC surveys are used to assess a commercial calibration or testing laboratory control over the identified critical

characteristics, these assessments are required to be performed on a 36-month cycle. The NRC recently endorsed a nine-month grace period for completion of these surveys during extenuating circumstances such as the current COVID-19 pandemic. This represents a maximum time between onsite surveys of 45 months. By comparison, ISO/IEC 17025 accreditations are typically performed on a 24-month cycle and two accreditation cycles represent 48 months. This 48-month period is quite comparable to the maximum period of 45 months for nuclear industry on-site surveys during periods of extenuating circumstances.

Based on all of the above, the industry still maintains a high degree of confidence that ABs world-wide are appropriately maintaining the integrity of the ISO/IEC 17025:2017 accreditation process during the pandemic in accordance with the ILAC MRA, ISO/IEC 17025:2017, and ISO/IEC 17011:2017 requirements. There are enough checks and balances in the process and robustness of the standards to conclude based on reasonable assurance that in the short term, there has been no loss of effectiveness of the accreditation process.

NEI Response to Part B

While the industry maintains our confidence in the ILAC Process for ABs that are signatory to the ILAC MRA, our position is going forward, additional controls are needed to ensure that remote accreditations are not overused and not substituted for on-site assessments. Therefore, revision 1 to NEI 14-05A, Sections 1.3, 4.2, 6, and Appendix A have been updated to recognize the use of remote accreditation assessments and to place a limitation on use of laboratories accredited based on a remote accreditation assessment. The update stipulates that users of the ILAC process per NEI 14-05A will be required to verify the laboratories being contracted to perform ISO/IEC 17025 accredited calibration or testing services have undergone an on-site accreditation assessment within the past 48 months or two accreditation cycles. This prevents a laboratory that performs calibration or testing for licensees and suppliers of basic components from receiving consecutive remote assessments. While it is believed the reliance on remote assessments will subside after the current pandemic is over, this new measure will assure that the spirit of ISO/IEC 17011 Section 7.9.3 is met by requiring verification of on-site accreditation assessments for laboratories performing work for licensees and suppliers of basic components.

In addition to requiring users of the NEI 14-05A to verify on-site assessments are utilized, a new procurement clause has been added to NEI 14-05A (Sections 1.3, 4.2, and Appendix A) which will be invoked in procurement documents to accredited laboratories. This procurement requirement will stipulate that as a condition for acceptance of the purchase order, the laboratory has achieved their accreditation to ISO/IEC 17025 based on an on-site assessment within the past 48 months. This will ensure that laboratories that achieved accreditation based on a remote accreditation assessment during COVID-19 pandemic cannot maintain their accreditation based on consecutive remote accreditation assessments. An on-site accreditation assessment will be required within 24 months following a remote assessment. Laboratories will still be required to certify to meeting the customer's purchase order

requirements. This was discussed with ABs and a selection of laboratories, all of which agreed to this approach. The imposition of this new procurement clause will be required effective June 2, 2021.

As mentioned above, the concept of remote assessment is something that was added to the 2017 version of ISO/IEC 17011 and ABs' implementation of this assessment technique will certainly be evaluated during the mandatory periodic peer reviews. NUPIC/NEI is scheduled to observe the 2020 peer evaluation of ANSI National Accreditation Board (ANAB). The NRC has been invited to observe this peer evaluation as well. The observation team will pay close attention to this area and these observations will be documented in a written report which will be available to the NRC. Any concerns will be evaluated for impact on our confidence on relying on the ILAC process to approve suppliers of calibration and testing services based on accreditation to ISO/IEC 17025:2017 in lieu of commercial grade surveys.